



PHASE 0 TOOLKIT MODULE: STARTING THE PROJECT

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UNEP-GEF Toolkits for the Development of National Biosafety Frameworks



Foreword

On 11 September 2003, the Cartagena Protocol on Biosafety entered into force. Between September 2003 and April 2005, 119 countries have answered this call and have ratified or acceded to the Protocol, one of the fastest ever rates of ratification for any international environmental agreement. This high level of participation has brought with it a high demand for capacity building for effective implementation of the CPB from many countries where the introduction, and safe use, of Living Modified Organisms (LMO) biotechnology is new to both national governments and to the general public. UNEP believes that, for the success of the Cartagena Protocol, it is crucial that countries are assisted in building their capacity to implement the Protocol.

This unprecedented demand for capacity building assistance has presented a challenge to CPB Parties, and for this reason, UNEP welcomed the adoption by the Council of the Global Environment Facility in November 2000 of the GEF Initial Strategy on Biosafety, which aimed to assist countries to be prepared for the coming into force of the Cartagena Protocol. One of the components of the Initial Strategy is the UNEP-GEF global project on the Development of National Biosafety Frameworks. This project started in June 2001 and is assisting over 100 countries to develop a draft for a national biosafety framework.

UNEP, in its capacity as an Implementing Agency of the GEF, has been providing administrative and technical assistance to the countries participating in the Development Project through its team of Regional Coordinators, and through the organization of regional and sub-regional workshops. In addition the UNEP Biosafety Unit has coordinated the production of four toolkits that provide guidance on the main steps in the development of a national biosafety framework. Revised versions of the toolkits, incorporating lessons learned from the early participating countries are presented here in this publication as part of the overall efforts that UNEP is making to the successful implementation of the Cartagena Protocol on Biosafety.

Klaus Toepfer
Executive Director UNEP

May 2005



A Biosafety Framework Development Toolkit

1. Overview

1.1 Purpose

The aim of this toolkit is to provide a practical “how-to” guide for countries to assist them in developing and implementing a project aimed at developing their draft National Biosafety Frameworks (NBF), under the UNEP-GEF Project on Development of National Biosafety Frameworks, which will enable them to make technical, political and local decisions on the safe transfer, handling and use of Living Modified Organisms (LMOs) and to meet the requirements of the Cartagena Protocol.

The toolkit is primarily intended for use by those institutions and staff responsible for designing and carrying out national projects to develop an NBF, namely:

- National Executing Agency (NEA),
- National Project Coordinator (NPC),
- National Coordinating Committee (NCC).

The toolkit will also provide practical advice for all other stakeholders involved in the preparation of the NBF.

1.2 Format

The toolkit is formatted in a flexible, dynamic manner that is tailored to meet the diverse needs of different countries, and that allows countries to select those tools and ideas that are most useful to them. It will also be developed in line with particular needs that arise during NBF development, and relevant amendments and additions made as a result of experience and inputs. The toolkit will utilise experiences and expertise from a diversity of sources – the UNEP/GEF Biosafety team, international and national experts, UNEP/GEF Pilot Biosafety Enabling Activity experience, etc. It will be an evolving document and will be continuously reviewed and revised in light of experiences of countries participating in the Global NBF project.

The toolkit will provide the sort of answers found in *Frequently Asked Questions (FAQ)* in order to provide guidance to countries on tackling problems and constraints that they encounter in designing and implementing their national projects.

1.3 Structure

The toolkit will be divided into four modules, each addressing one of the phases listed in the national project document:

- Phase 0** the vision (or rationale) of the project design, its guiding principles, and the establishment of institutional and management structures.
- Phase 1** the instigation of surveys and the preparation of inventories in the different sectors pertaining to biosafety and biotechnology within the country, including their entry into national databases.
- Phase 2** the identification of stakeholders, and the consultation, analysis, and training activities needed to identify the priorities and parameters for the drafting of the National Biosafety Framework (NBF).
- Phase 3** the drafting of the NBF including consultation with stakeholders for their endorsement.

1.4 This toolkit module

Phase 0 – Starting The Project

The phase 0 is divided into the following sections:

- Project rationale
- Institutional Structure
- Project design (budget, workplan etc.)
- Protocol requirements

2. Project rationale

Why does a country need a National Biosafety Framework (NBF)?

The first step for a country in developing its NBF is to develop a national vision for biosafety, i.e. WHY does the country need a national biosafety framework?

The main reason for a country to develop its NBF is to put in place an enabling mechanism for making decisions on the safe transfer, handling and use of living modified organisms (LMOs).



The following key principles, derived from the Cartagena Protocol on Biosafety, provide a useful guide for the development of a country's NBF:

- *Providing Choice* – a country is enabled to make an informed choice on whether it wants to import or use LMOs or not. Inevitably, all countries will be faced with this question at some time in the future and the NBF will enable them to make a decision on a rationale, participatory and informed way.
- *Ensuring Safety* – development of an NBF will enable a country to set in place the tools that will enable it to assess, evaluate and manage any potential adverse effects associated with the transboundary movement, transit, handling and use of LMOs on the conservation and sustainable use of biological diversity taking also into account risks to human health, as well as socio-economic considerations.
- *Giving a Voice* – by promoting participation by all stakeholders in the formulation of the NBF, and in future decision making on the use of LMOs, the country will enable all stakeholders to have a voice.
- *Building Capacity* – a country will need to strengthen its human resources and institutions for both the technical aspects of risk assessment and for informed and participatory decision making.
- *Assuring Sustainability* – by setting in place the necessary tools, the project will put in place a NBF that will enable the country to make decisions on the use of LMOs on an on-going basis.
- *Implementing the Cartagena Protocol* – the NBF will enable the country to meet the requirements of the Protocol and provide the country with an adequate level of protection for the safe transfer, handling and use of LMOs

3. Institutional Structure

In setting up Institutional Structures for the project, terms of reference are supplied in the National Project Document, but a number of additional points need to be taken into account as these components are developed.

The core institutional structure of the project consists of three components:

- National Executing Agency (NEA),
- National Coordinating Committee (NCC), and
- National Project Coordinator (NPC).

Each of these components needs to have clearly defined roles and responsibilities for the Project to be effective. The project must be well founded in its institutional structures if it is to have credibility and effectiveness over the life of the project. In addition these components may provide the basic institutional arrangement for the future operation of the National Biosafety Framework. The appointment of appropriate agencies/bodies/individuals with necessary experience and capacity is therefore very important.

3.1 The National Executing Agency (NEA)

The National Executing Agency (NEA) is the legal entity responsible for executing the UNEP-GEF Project for the development of a National Biosafety Framework. The identification of a single executing agency is crucial in ensuring the efficient operation of the National Project and its completion within the expected timeframe of 18 months.

The role of the NEA (see Box 1 below) is considered to be central in the effective management and successful completion of the Project. Its main task consists of coordinating the full participation of all governmental agencies with mandates relevant to the Cartagena Protocol on Biosafety as well as the private and public sectors into the Project.

Some specific criteria, related to its planned activity, could help in the identification of the most appropriate organization as the NEA:

- A body with a central role in biosafety issues.
- The capacity of the agency to manage administrative functions as well as to coordinate other agencies.
- A possible continuation of its role within the future National Competent Authority.
- A transparency of internal decision processes.
- Experience in communicating with other agencies as well as the private and public sectors.
- A clear acknowledgement from other relevant agencies and organizations of its role as a coordinator.

In many aspects, the functions of the NEA in the National Project may anticipate some of the coordinative tasks required within the Competent National Authority/ies, which Parties to the Protocol must designate in the future for the implementation of the Cartagena Protocol on Biosafety¹.

The development of the National Biosafety Framework will, in any case, help the country to identify the necessary capacities, within or outside the NEA, for the future Competent National Authority/ies.

Please note, in this context, that the IUCN draft guide indicates: *"While the competent national authority (or authorities) is responsible for carrying out administrative functions under the Protocol vis-à-vis other Parties, the decision-making process under a Party's national biosafety framework for reaching a decision on the proposed import of an LMO is likely to involve a wide range of national authorities."*

¹ According to the Art. 19 of the Protocol, each Party will "designate one or more competent national authorities, which shall be responsible for performing the administrative functions required" by the Protocol. The competent national authority will interface with notifiers, Parties and the Biosafety Clearing House (BCH) of the CBD. According the IUCN draft guide to the Cartagena Protocol the Competent National Authority will: a) receive notification of proposed transboundary movement of an LMO that falls within the scope of the AIA procedure (Article 8); b) acknowledge receipt of the notification (Article 9); c) request further information from the notifier, if necessary (Article 9; Article 10); d) communicate the decision of the Party of import to the notifier and the Biosafety Clearing House (with reasons where required) (Article 10(3)); e) respond to requests by the Party of export or notifier to review decisions (Article 12); and f) consult with the notifier where necessary on treatment of confidential information (Article 21)



*Extracted from page 5 of the National Project Document template:
Roles And Responsibilities*

4.1 National Executing Agency

The Name of the Agency, acting as the 'National Executing Agency' (NEA), will be the legal entity responsible for executing the National Project. The NEA will be appointed by the National Government after consultation with the GEF and ICCP focal points. The Terms of Reference (TOR) for the NEA are in Annex 1.

*Extracted from page 13 of the National Project Document template:
Draft Terms of Reference for the NEA:*

- The National Executing Agency (NEA), in addition to other duties given to it by the National Government, will:
- Establish the National Co-ordinating Committee (NCC);
- Appoint a full time National Project Co-ordinator (NPC), taking into account the sustainability of national biosafety activities on completion of the National Project;
- Provide the necessary scientific, technical, financial and administrative support to the work of the NCC, working in close cooperation with relevant government agencies, the scientific community and the public and private sectors;
- Ensure that regular reports, financial accounts, and requests are submitted to UNEP as set out in section 6;
- Review all documentation deriving from the National Project and any other relevant documentation to ensure that these are consonant with National Government;
- Submit the final version of the National Biosafety Framework no later than eighteen months from signature of this Memorandum of Understanding.

3.2 National Project Coordinator (NPC)

The National Project Coordinator (NPC) is the individual responsible for the management, coordination and oversight of the UNEP-GEF Project, as well as the monitoring and reporting on the progress of the development of a National Biosafety Framework in his/her country. This position needs to be a full time job for the duration of the Project.

As the secretary to the NCC, the NPC will act as the link between the NCC (the consultative body of the institutional structure) and the NEA (the executive body of the institutional structure), as well as the liaison between the overall national institutional structure and the UNEP-GEF Biosafety Team. The role of the NPC is therefore catalytic to the effective and efficient operation of the various activities conducted under the Project.

As Secretary to the NCC and link to the NEA, the main tasks of the NPC include the following activities:

- Organize National Coordinating Committee meetings;
- Oversee the progress of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Foster, establish and maintain links with other related national and international programmes and National Projects;
- Prepare and oversee the development of Terms of Reference for National Project consultants and experts;
- Organize, contract and manage the consultants and experts, and supervise their performance;
- Coordinate and oversee the preparation of the outputs of the Project;
- Ensure that all relevant information is available to the NCC about Government, private and public sector activities, which impact on modern biotechnology;
- Coordinate and report the work of all stakeholders under the guidance of the NEA and the NCC;
- Prepare and submit regular progress and financial reports to the NCC as required.

As the liaison point to the UNEP-GEF team, the NPC will:

- Prepare detailed workplan and budget under the guidance of the NCC;
- Manage the National Project finance, oversee overall resource allocation and where relevant submit proposals for budget revisions to the NCC and UNEP.
- Ensure that all the activities are carried out on schedule and within budget to achieve the stated outputs;
- Prepare and submit quarterly progress and financial reports to UNEP.

Considering the wide range of the envisioned activities for the NPC, the following criteria may help in the identification of the appropriate candidate:

- A degree in Science or Law
- An in-depth knowledge about the Cartagena Protocol
- Ability to command some influence and respect among stakeholders in all biosafety activities at the national level.



*Extracted from page 5 of the National Project Document template:
Roles And Responsibilities*

4.2 National Co-ordinating Committee

The National Co-ordinating Committee (NCC) will be established by the National Executing Agency (NEA) to advise and guide the preparation of a National Biosafety Framework. This committee will include representations of all government agencies with mandates relevant to the Cartagena Protocol on Biosafety and will include representations from the private and public sectors. This Committee will be multi-disciplinary and multi-sectoral in fields relevant to the Cartagena Protocol on Biosafety. The NEA may also establish sub-working groups as necessary with clear Terms of Reference as appropriate. The Terms of Reference (TOR) for the NCC are in Annex 1.

*Extracted from page 13 of the National Project Document template:
Draft Terms of Reference for the NCC:*

b) The National Coordinating Committee (NCC) will work together as a team on management of the National Project and meet at least on a quarterly basis with the following duties:

- Develop a common understanding of what is needed to expedite the preparation of a National Biosafety Framework;
 - Oversee the preparation of the National Biosafety Framework
 - Approve the detailed workplan and budget produced by the NPC;
 - Mobilise necessary expertise, as needed for the proper execution of the National Project outputs;
 - Provide overall policy advice on the implementation of the National Project;
 - Review and advise on the main outputs of the National Project;
 - Ensure that information on the implementation of the National Project as well as the National Project outputs is brought to the attention of local and national authorities for follow up;
 - Assist in mobilising available data and ensure a constant information flow between all concerned parties;
 - Allow for effective communication and decision-making between the National Project Coordinator and other actors;
 - Ensure that the environmental policy of the Government is fully reflected in the National Project documentation;
 - Review and approve the Biosafety Assessment, National Project Outputs and Framework Documents.
- The National Project Co-ordinator (NPC) will act as the secretary of the NCC

3.3 National Coordinating Committee

The National Coordinating Committee (NCC) will be established by the National Executing Agency (NEA) to advise and guide the preparation of a National Biosafety Framework.

This Committee needs to be multi-disciplinary and multi-sectoral as it will be the major decision making body to be involved in the practical development of the NBF.

The Committee may need to adapt itself to external events and to change its composition and functions as the project develops and it is important not to be directive in its definition at the start, so the NCC can respond to changing circumstances and widen its membership as the process of stakeholder consultation goes on and brings out key players that need to be involved in the process.

The NEA may establish sub-working groups as necessary, with appropriate Terms of Reference. These might look at specific issues at a more technical level (e.g. risk management strategy, import & quarantine procedures etc.). This ability to divide up tasks or solve problems needs to be there in the regulations of the NCC.

Who should be represented on the NCC?

This committee needs to include representations of all government agencies with mandates relevant to the Cartagena Protocol on Biosafety and will include representations from the private and public sectors. A representative of the NEA, in addition to the NPC, would sit on the NCC as a voting member. A broader list of the type of organizations to be invited can be derived from the list provided in the section on "Who should be involved in developing the NBF".

The most effective size of the NCC is suggested as 10 to 15 members including representatives from industry and public sectors, reflecting a full representation of organizations or groups that could be interested in Biosafety. This would allow a balanced representation by all sectors while ensuring the ability of the Committee to respond to its mandate.

Who chairs the NCC?

The question of who chairs the meetings is an issue to be considered carefully, as this role will have a major influence on the development of the NCC. The Chair of the NCC may therefore need the following qualities:

- A recognized authority in the country on issues related to biosafety.
- An ability to listen to all different views and help find appropriate and workable solutions
- A decisive and incisive mind, able to tackle the very large array of questions that will occur.
- Experience in chairing public meetings and dealing with the media as a number of contentious and difficult issues are likely to come up.
- A leadership ability that enables the NCC to work effectively in carrying out the project activities.

Whether the NCC chooses a permanent chairman or a rotating position is the choice of the country, but continuity in the position through the project will be likely to be valued highly by all parties.

How does the National Project Coordinator relate to the NCC?

The NPC is appointed by the National Executive Agency. However the NPC reports principally to the NCC and is responsible to the NCC, as well as the NEA, for achieving the Project outputs. Since the NPC acts as a secretary to the NCC and is a non-voting member of the group, the NCC will have ample opportunity to monitor the delivery of results over the project life.



How to organize NCC meetings?

The role of the NCC is likely to be most successful if there is continuous follow up of issues in regular meetings. Most countries would benefit from meetings held every three months, as a minimum.

Invitations to NCC members should be sent out by the NPC giving enough time for members to attend, and all arrangements for the venue and the dissemination of papers for a meeting, etc will need to be done by the NEA and NPC.

Travel costs to the meetings should be provided to all NCC members, at project expense, at the most economical and reasonable rate and a payment to cover meal costs may be seen as a necessary part of the arrangements, if refreshments are not provided by the hosting organization. It would not be acceptable to pay sitting allowances to NCC members. The NPC and his assistants would normally manage the travel and subsistence payments.

It is often helpful to get better representation at meetings by holding them in different locations around the country, and the travel costs can help provide for this flexibility. The cost of holding an event such as the NCC meetings would normally be considered as a part contribution from the Government.

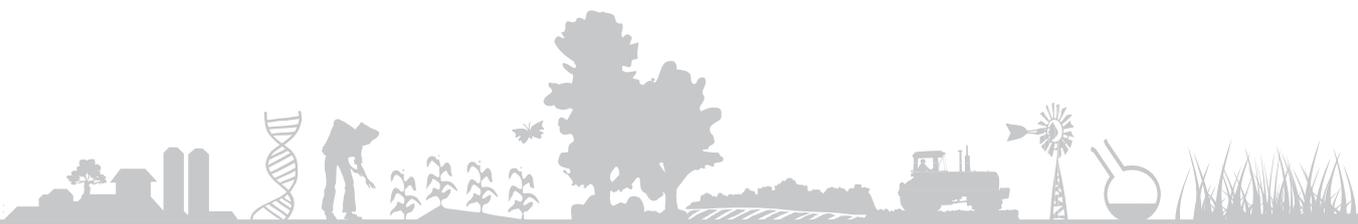
What does the NCC do?

The NCC has the following specific tasks, as detailed in Box 3 below and in the TORs, which we have expanded upon to give clearer explanations on various aspects of the work:

- Develop a common understanding of what is needed to expedite the preparation of a National Biosafety Framework. This needs to include listening to all the divergent opinions and a thorough reading of the results of the surveys and inventories. Later, it will be looking at draft sections of the NBF and helping to get a result that reflects national needs and meets international obligations.
- Approve the detailed workplan and budgets produced by the NPC and oversee the overall resource allocation and propose and/or agree on proposals for budget revisions with the advice of the Regional Coordinator for the project in UNEP. Ensure that delivery of inputs is on time and within budget to achieve the stated outputs
- Oversee the preparation of the National Biosafety Framework, and look at the work produced by the NPC and his/her team of experts. This will involve critical review of the outputs and the questioning of areas where there is uncertainty or a lack of clarity.
- Approve the intermediate and final stages of the NBF
- Ensure that the appropriate and necessary expertise is

mobilized for the various activities, as needed for the execution of the National Project outputs and support the NPC in his/her requests for resources.

- Provide overall policy advice on the implementation of the National Project, so that government agencies, scientists, industry, the general public and the NPC are made aware of what is expected of them.
- Review and advise on the main outputs of the National Project, giving clear directions on what are the next steps and whether remedial actions are needed.
- Ensure that information on the implementation of the National Project, as well as the National Project outputs, is brought to the attention of local and national authorities for follow up. This means that the NCC is accountable to the relevant authorities and should keep them informed and involved where it is possible.
- Assist in mobilising available data and ensure a constant information flow between all concerned parties. The NCC may decide to give press releases and give out material on public sites and on websites, but must ensure the materials produced have the widest possible audience.
- Allow for effective communication between the NPC and other actors, supporting the role of the NPC in dealing with other organizations and groups and ensuring that he/she has the full support of the NCC in entering into negotiations with other parties while following NCC guidance.
- Ensure effective communication with the relevant authorities, institutions and government departments
- Ensure that all relevant Government policies are fully reflected in the National Project documentation. This is a key function of the NCC, which should ensure that overlaps and gaps of coverage in the national framework and eventually any legislation are avoided.
- Review and approve the overall surveys and resulting inventories, as well as all the outputs from the Project and the resulting draft versions of the National Biosafety Framework.
- Approve any revision of the workplan and budget produced by the NPC.
- Advise Government of the Project's conclusions and make recommendations on the strategy and framework components, content and timing of possible legal instruments as required.
- Seek solutions to operational and political difficulties in reaching the objectives of the NBF.
- Act as a discussion forum to air differences and listen to a variety of views and record the process.



*Extracted from page 5 of the National Project Document template:
Roles And Responsibilities*

4.3 National Project Co-ordinator

The National Project Coordinator will be appointed by the National Executing Agency, after consultation with UNEP, on a full time basis for the duration of the National Project. The National Project Coordinator shall be responsible for the overall co-ordination, management and supervision of all aspects of the National Project. He/she will report to the National Co-ordinating Committee and UNEP, and liaise closely with the chair and members of the National Coordinating Committee and National Executing Agency in order to coordinate the work plan for the National Project. He/she shall be responsible for all substantive, managerial and financial reports from the National Project. He/she will provide overall supervision for any staff in the NBF Team as well as guiding and supervising all other staff appointed for the execution of the various National Project components. The Terms of Reference (TOR) for the NPC are in Annex 1.

*Extracted from page 14 of the National Project Document template:
Draft Terms of Reference for the NPC:*

- The National Project Coordinator (NPC) will carry out the following tasks:
- The National Project Coordinator (NPC) will act as the secretary of the NCC
- Coordinate, manage and monitor the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Organize National Coordinating Committee meetings;
- Prepare detailed workplan and budget under the guidance of the NCC;
- Ensure effective communication with the relevant authorities, institutions and government departments in close collaboration with the National Coordinating Committee;
- Foster, establish and maintain links with other related national and international programmes and National Projects;
- Prepare Terms of Reference for National Project components, consultants and experts;
- Organize, contract and manage the consultants and experts, and supervise their performance;
- Coordinate and oversee the preparation of the outputs of the NBF;
- Manage the National Project finance, oversee overall resource allocation and where relevant submit proposals for budget revisions to the NCC and UNEP.
- Manage the overall National Project ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Coordinate the work of all stakeholders under the guidance of the NEA and the NCC and in consultation with the UNEP Global National Project Team;
- Ensure that information is available to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
- Prepare and submit to UNEP and the NCC, regular progress and financial reports as set out in Section 6.

3.4 Who should be involved in developing the NBF?

Article 23 of the Cartagena Protocol places a strong emphasis on participation *and* on increasing public awareness and education so that stakeholders have the relevant knowledge and information to enable them to participate effectively in decision making at the national level on the safe transfer, handling and use of living modified organisms (LMOs).

Participation is a simple word that means “*sharing or taking part in*” and implies how and to what extent people are able to express their views, to take part in decision-making, and contribute to policy formulation. The aim of participation is to build partnerships, so that it is possible to harness the collective energy and potential of all stakeholders in developing and implementing national policies.

Stakeholders are all those with an interest or stake in biosafety, i.e. in the safe transfer, handling and use of (LMOs) in the country.

Two complementary forms of participation could be relevant in the development of a NBF: *interactive participation* and *participation by consultation*.

During the preparatory stages of developing their NBFs, countries need to involve stakeholders in the joint analysis of biosafety issues and challenges facing the country, and in the identification of the components of NBFs. This form of participation helps to promote ownership and commitment to the NBF, and enables a collective decision by all stakeholders on the course of action.

This section of the toolkit is therefore designed to help countries to both identify *who* are the stakeholders in the NBF, and *how* to involve them in the development of their NBF. This will lay the foundations for their later involvement in the implementation of the NBF, i.e. in decision-making on the safe transfer, handling and use of LMOs.

Who participates?

In answering the question “Who participates?”, the NEA, and subsequently the NCC, have to identify the stakeholders who will be involved as partners in the development of the NBF.

A useful exercise for the NEA is to carry out a stakeholder analysis (see Annex) in order to better understand who should be involved. It is important that this is done in a systematic manner to ensure that all stakeholders and the roles and responsibilities in the NBF are identified.

Although all individuals could be considered stakeholders in specific circumstances, effective decision-making requires the identification of representative groups of stakeholders, which could play an effective role in consultations.

The following checklist of stakeholder categories could help in the identification of potential stakeholders within a country:



- **National Government** – Those government agencies likely to be directly or indirectly involved in the introduction and/or use of LMOs.
- **Community-based organisations** – groups of people with common interests such as consumers, women, youth, religious groups, traditional social groups, special interests (e.g. farmers), etc, whose lives and interests could be directly or indirectly affected by the impacts of the introduction or use of LMOs.
- **The public sector** – including national and international NGOs, academic and research institutions, schools, the media, particularly those with knowledge related to the safe introduction and use of LMOs;
- **The private sector** – primary industries (agriculture, horticulture, etc.), secondary industries (manufacturing, processing, etc), service industries, small businesses, co-operatives, banks, insurance, etc, particularly those who are likely to be directly or indirectly involved in the introduction or use of LMOs.
- **Traditional and spiritual leaders** – those involved in the traditional systems of governance within the country or in the main religions within the country.
- **Local government** – elected representatives, management staff, field and operational staff, local government institutions, etc.

How do we promote participation?

At this early stage, the NEA has to be mindful about how they can provide an *enabling environment* that will support participation by all stakeholders. The following points could be helpful in this process.

- Commitment to a more open system of decision-making on issues related to biosafety, within government agencies.
- Creating a trustworthy environment that enables all stakeholders to take part in the decision-making process.
- Access to appropriate participatory mechanisms for all stakeholders.
- Information – effective participation is dependent on all stakeholders having access to relevant information so that they are able to make decisions based on sound and up-to-date information.
- Capacity building – all stakeholders should also have the necessary skills and have access to appropriate tools to enable them to participate, both in terms of their right to participate in decision-making, and in terms of their responsibility to contribute to the implementation of the NBF.
- Time – effective participation is only possible when sufficient time is allowed within the decision-making processes of government for consultation with the relevant stakeholders.

3.5 Identifying stakeholders

This exercise is best carried out by the NEA with the participation of members of the NCC so as to ensure that stakeholders with a range of interests are represented. This exercise is in two parts: the first is a brainstorming exercise to identify stakeholders in the NBF and the second part is to work out their potential contribution to the development of the NBF and its implementation.

Part A: Brainstorming

The purpose of this exercise is to generate a large number of ideas quickly about possible stakeholders, and to encourage creative and flexible thinking in identifying possible stakeholders.

Procedure

- Ask the group to write down in 10 minutes who they consider to be stakeholders i.e., those with an interest in biosafety and the development of the NBF.
- Request participants to list all stakeholders with a potential interest in biosafety, that come into their head without censorship or discussion, and as fast as possible. Encourage people to build on each other's ideas.
- Write all names down on a board.
- At the end of the session, take 20-30 minutes to analyse the ideas by grouping them into sets of stakeholders with common interests. Look particularly at the potential involvement or impact in terms of benefits and costs, both direct and indirect.
- Summarise the results by listing the groups of stakeholders up on a board

Part B: Roles and responsibilities

The purpose of this is to determine the roles and responsibilities of different stakeholders in different stages of the development of the NBF.

Procedure

- On a board, draw a matrix with the names of all stakeholder groups (from the contributions of all interest groups in Part A) down the left-hand side.
- Across the top, list the main tasks for the NBF – collection of information, analysis, setting priorities and identifying options, preparation of the components of the NBF, formulation, and its implementation.
- List HOW each stakeholder group can be involved in those areas of the NBF that are most relevant to them and where they have most to contribute.



Stakeholders matrix

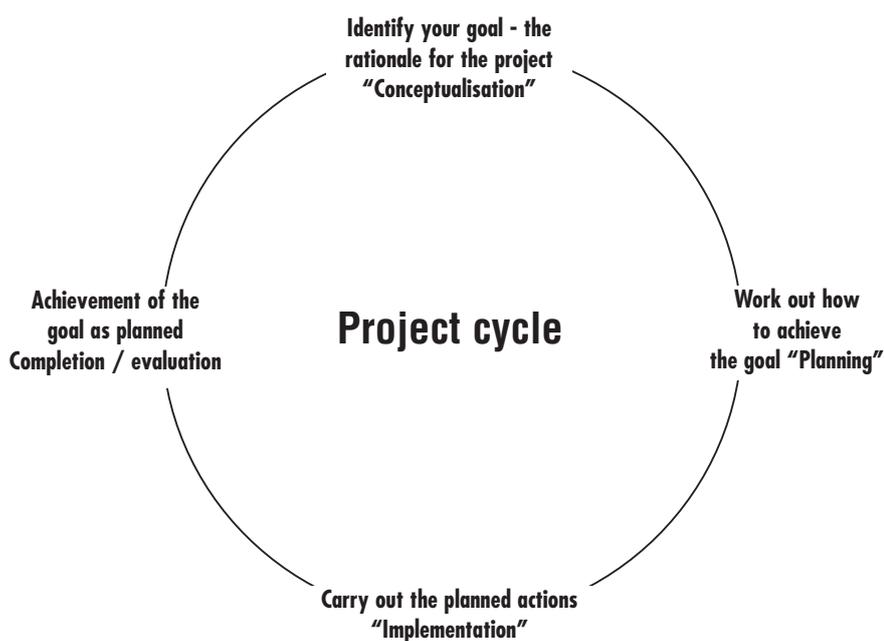
Stakeholders	Tasks				
	Collection of information	Analysis of issues	Setting priorities and identifying options for the NBF	Preparation of of the four components of the NBF	Implementation of of the NBF
1. Govt agencies, etc					
2. Primary producers, farmers, etc					
3. Consumer groups					
4. Researchers and research institutions, etc					
5. And so on					

4. Project design

Countries have been provided with a sample national project document, which they need to adapt and tailor to their own national needs, priorities and situation. This is one of the first management tasks of the NPC – to take the actions set out in the work plan of the sample and to translate them to specific actions and strategies that will enable them to work out How they will carry out their own national project.

This should take account of existing opportunities and constraints within their country, as well as their priorities. This step is also important to enable the country and the management team to claim ownership of the project.

We suggest that the NPC take a project cycle management approach (see below) to help them do this.





The different stages of the project cycle are part of a continuous process with each step building on the preceding one.

- The thinking stage helps the country to identify “Why” it needs to develop a national biosafety framework (e.g. the section 1, project rationale) – this is the goal or rationale for the project.
- The planning stage helps the country to identify “How” the project is to be carried out to achieve the goal, given existing constraints and opportunities. In other words, translating the model national project document into an operational plan, i.e. the implementation strategy and work plan. This will provide a more complete picture of how the project can be best carried out to achieve the project goal.
- The implementation stage is carrying out activities as planned. This requires a flexible and creative approach to tackle problems as they come up by constantly adapting the plan to the real situation, while keeping the goal in mind. This is best done through the active participation of all stakeholders through the project’s institutional and consultative mechanisms.
- Finally, at its completion, the country can check whether the project has achieved its original goal, and what the lessons are for the future in terms of further steps.

The steps in the project management cycle can be linked together systematically by the NPC through a logical framework analysis “logframe”, which provides an analytical tool for planning, design and management of projects (See the “logframe” later in this section). This systematic approach helps to link the hierarchy of goal, objective, outputs and activities set out in the national project document.

To implement the project, the NPC can use the following management tools:

Management tools are practical tools that project managers can use to manage project resources in the most effective and efficient way to help achieve project aims:

- A *work plan* that sets out the tasks necessary to achieve the project results and purpose; these specify when tasks are to be carried out, and who is responsible for what tasks. The work plan includes timetables for implementation, major milestones, and regular reporting requirements to help ensure that everyone knows *what* they are expected to do and by *when*.
- A *budget* is a summary of the finances of a project: how much specific activities and inputs will cost, when the money will be

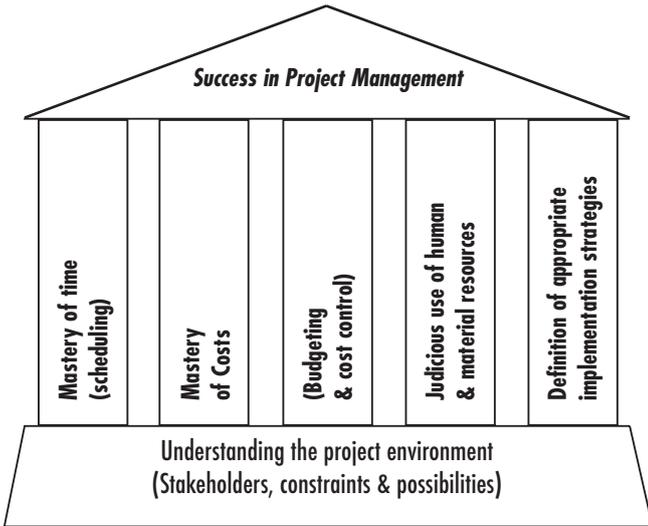
required and where the money will come from (government and/or GEF).

- The *human resources* required for the project. This includes the contributions from all stakeholders, including the people required for carrying out project activities. It also includes requirements for technical assistance from national and outside sources, as well as capacity building activities such as training and support systems.
- A *stakeholder analysis* (section 2) will help the NPC and the NCC to identify who should be involved in the project and to identify their roles and responsibilities so that all parties then have a clear understanding of what they are expected to do and by when. A clear management structure is necessary to ensure that differing views are accommodated within the project and that tasks are carried out on time without duplication of effort, and that when things go wrong, remedial action is taken.
- *Monitoring and feedback* help ensure that all participants in a project learn from their experiences and use these lessons to improve the current project and future implementation. One of the major roles of the NPC and the NCC will be to ensure that the project stays on track through a constant flow of information to all stakeholders for making the decisions needed to keep the project on track.

Among the tools cited above, the preparation of a detailed project work plan with an implementation strategy is one of the most important actions to be undertaken by a project manager on a new project.

The project logframe (see later part in this section) sets the relation between objectives outputs and activities, but does not offer clues as to how these activities should be carried out by the project management team. To that end we need a *good, workable implementation strategy* identifying choices as to the best way to implement specific activities, and the resulting *work plan which identifies the time frame, the use of resources (human and material) and the costs* associated with the implementation of each project activity so that it achieves expected results. A good work plan also identifies who is responsible for carrying each activity (in many cases these activities are carried out by various actors, and a breakdown of responsibilities is needed). Success is the result of this skilful combination of factors, illustrated as follows:





Once the details of activities and their associated costs have been well identified, budgeting becomes much easier. Budgeting is the activity that matches the costs of the project with the amounts of money available to the project. Typically donor organizations specify, as a matter of policy, what type of expenditures can be made under a project and what are the proportions between these types. Costs are therefore related by type to the allowed budget until costs and planned allocation correspond to each other. This is also why implementation strategies may need to be revised in function of their associated costs. The budgeting exercise can be a complex one and requires an understanding of allowed expenditures. Because of this, specific annexes and footnotes have been inserted into the model project document, and are being reproduced in annex of this document for ease of reference.



From page 17 of the National Project Document template:
ANNEX 3: Suggested budget lines related to work plan

ACTIVITIES	BUDGET LINES
1. Appointment of a full time National Project Coordinator (NPC) for the duration of National Project	1101 (NPC costs) 1601 (staff travel and per diem)
2. Office set up and running through Project life	1301 (personnel costs) 1601 (staff travel and per diem) 4101 (office supplies) 4120 (purchase of relevant material) 4201 (computers and other equipments) 4301 (premises costs) 5101 (equipment maintenance) 5220 (reporting costs) 5301 (communications costs)
3. Establishment of National Coordinating Committee (NCC)	See Activity # 4.
4. Regular NCC meetings held (quarterly?)	1601 (members travel and per diem)
5. Communicate to UNEP the name and contact details of NPC, and composition of the NCC	
6. Detailed planning and oversight of all surveys to be carried out by NPC	
7. Submit 1 st quarterly progress report to UNEP	
8. Survey of existing uses of biotechnology and the arrangements for safe use of biotechnology, including review and assessment of existing legislation that may impact on the use of modern biotechnology. (This may include phyto-sanitary, pesticide, herbicide, import and export legislation and guidelines)	Possible range of options to consider: A) NPC to carry this out B) 1201 (individual consultant) C) 2201 (sub-contract to governmental agencies) D) 2301 (subcontract to private firms)
9. Survey on existing national, bilateral and multilateral co-operative programmes in capacity building, R & D and application of biotechnology;	Possible range of options to consider: A) NPC to carry this out B) 1201 (individual consultant) C) 2201 (sub-contract to governmental agencies) D) 2301 (subcontract to private firms)
10. Survey on existing national biosafety frameworks in the countries of the sub-region;	Possible range of options to consider: A) NPC to carry this out B) 1201 (individual consultant) C) 2201 (sub-contract to governmental agencies) D) 2301 (subcontract to private firms)



11. Survey on existing mechanisms for harmonisation of risk assessment/risk management, mutual acceptance of data and data validation;	Possible range of options to consider: A) NPC to carry this out B) 1201 (individual consultant) C) 2201 (sub-contract to governmental agencies) D) 2301 (subcontract to private firms)
12. Survey on the extent and impact of release of LMOs and commercial products.	Possible range of options to consider: A) NPC to carry this out B) 1201 (individual consultant) C) 2201 (sub-contract to governmental agencies) D) 2301 (subcontract to private firms)
13. Submit 2 nd quarterly progress report to UNEP	
14. Identify how information should be stored and managed for input in the BCH and for promoting public participation	Possible range of options to consider: A) NPC to carry this out B) 1201 (individual consultant) C) 2201 (sub-contract to governmental agencies) D) 2301 (subcontract to private firms)
15. Create a database listing national experts in fields related to biotechnology and biosafety, as well as in fields relevant to risk assessment and risk management of LMOs.	4103 (computer software) Possible options A) NPC to carry out B) 1201 (individual consultant) C) 2201 (sub-contract to governmental agencies) D) 2301 (subcontract to private firms)
16. Create a database detailing relevant outputs of the national surveys	4103 (computer software) Possible options: A) NPC to carry out B) 1201 (individual consultant) C) 2201 (sub-contract to governmental agencies) D) 2301 (subcontract to private firms)
17. Submit 3 rd quarterly progress report to UNEP	
18. Organise national workshop for the identification and analysis of options to implement relevant provisions of the Cartagena Protocol on Biosafety	3201 (training and workshops)
19. Produce public awareness material and access to information for stakeholders	5201 (publication and outreach materials)
20. A national workshop to review the findings of the surveys, identification of gaps, needs and priorities;	3201 (training and workshops)
21. Training workshops on risk assessment and risk management;	3201 (training and workshops)
22. Stakeholder workshops on the national biosafety framework targeted to relevant stakeholders including public and private sectors and, in particular, national legislators;	3201 (training and workshops)
23. Preparation of material for a sub-regional workshop on harmonisation efforts in the preparation of the national biosafety frameworks and sharing of experiences;	3201 (training and workshops)



24. Public awareness workshops on the national biosafety framework with the participation of NGOs, consumer organisations, the scientific community and the private sector including farmers, the food and feed industry and the chemical industry.	3201 (training and workshops)
25. Submit to UNEP national workshop reports, including lists of participants and their constituencies.	5220 (reporting costs)
26. Attendance at regional or sub-regional workshops as they occur	Budgetted for within global programme
27. Submit 4 th quarterly progress report to UNEP	
28. Stakeholder workshop to identify key components of NBF	3201 (training and workshops)
29. Prepare a National Biosafety Framework, including procedures for the safe application of biotechnology in accordance with the Cartagena Protocol on Biosafety (administrative, legislative, risk assessment and public participation systems)	Possible options A) NPC to carry out B) 1201 (individual consultant) C) 2201 (sub-contract to governmental agencies) D) 2301 (subcontract to private firms)
30. Prepare a National Biosafety Framework, including procedures for the safe application of biotechnology in accordance with the Cartagena Protocol on Biosafety (administrative, legislative, risk assessment and public participation systems)	Possible options A) NPC to carry out B) 1201 (individual consultant) C) 2201 (sub-contract to governmental agencies) D) 2301 (subcontract to private firms)
31. Submit 5 th quarterly progress report to UNEP	
32. Stakeholder workshop to discuss draft and final components of NBF	3201 (training and workshops)
33. Identify follow-up actions as appropriate for the Implementation of the National Biosafety Framework	
34. Prepare and agree with UNEP on Terminal Report	5220 (reporting costs)
35. Publish inventories, reports, regulation and guidelines, etc. As appropriate	5201 (publication and outreach materials)
36. Submit final report to UNEP	



From page 21 of the National Project Document template: Annex 4-Budget in UNEP format Footnotes to the Budget

Footnotes to the Budget

As a general rule, budget lines finishing with00 are main headers while budget lines finishing by ...99 are subtotals for those main headers. Each main header identifies different categories of expenditures and the system requires that the different cost items identified under specific activities be included under these categories. Budgeting must therefore be the result of a careful work planning exercise implying some decisions on the implementation strategy for specific activities of the project. Budgeting is therefore not an independent exercise, and must be justified by the work plan.

National Project Personnel: National Project Coordinator (Budget Line 1101)

For the purpose of this project only the NPC is considered the only full time permanent professional staff of the project. The cost of this category of personnel, with substantial expertise as well as managerial responsibilities, should be charged on this Budget Line. This line is only for direct contracting of individual services (not to be confused with the contracting of institutions even where these institutions lend their full time staff to the project).

Consultants: Individual Consultants (Budget Line 1201)

Each planned consultancy should be identified in the work plan and contain the costs of fees and travel. The consultants are likely to be needed in surveys, workshops, legal and technical reviews and advice, and may be employed for short periods. It would be expected that national consultancies would form the bulk of this budget line.

Administrative Support Component: Personnel (Budget Line 1301)

The cost for administrative personnel should be reflected on this line and should include clerical, secretarial/administrative support as well as logistical support on the basis of an itemized work plan.

Travel Costs: travel for project Staff and NCC members and per diems: (Budget Line 1601)

This line is for project staff and NCC travel and mission costs related to the implementation of the present project only. It is to be used only for travel and missions outside the area of normal project operations. An estimate for such costs should be prepared covering the entire project duration as part of the overall activity planning of the project at formulation time. This cost should be proportionate to the cost of the activities to be undertaken, and should include only necessary travel related to project implementation. Mission reports should be produced covering the use of these funds and the implementation of project activities.

Sub-contract Component (20)

This component is for contracting entities other than individuals (Budget Line 1101 and 1301). Sub-contracts can be for either goods or

services. In this project, we will consider service subcontracts as a way to contract entities with the required expertise to assist in implementing activities of the project.

Sub Contract for supporting organizations: Sub-contract to government agencies (Budget Line 2201)

This line is to be used only for public and government bodies that possess a specific technical expertise necessary for the implementation of project activities. Such institutions must have a public charter. In the context of this project, there is an expectancy that as much as possible the services provided by government bodies will fall into the category of 'government contribution'.

Sub Contract for Commercial Purposes: Sub-contacts to private firms (Budget Line 2301)

This line is to be used only for the contracting of entities of a private nature, who possess a specific technical expertise necessary for the implementation of project activities. This is the case for instance of the contracting of a consulting firm to carry out a series of activities for the project. This modality can be in some instances more advantageous than the recruitment of individual consultants when the range of services is wider than the skills of any individual.

Group training: Training and Workshops (Budget Line 3201)

In this project, only group training will be considered, particularly the series of workshops planned as part of the framework. Such costs have to be estimated before hand taking into account the venue, duration, timing, needs for facilitation and the expected number of participants. Each training activity must have terms of reference outlining specific objectives and a strategy to achieve them.

Expendable equipment (Budget Lines 4101, 4103 and 4120)

Expendable equipment is, for all practical purposes, equipment with a life cycle shorter than the expected duration of the project (around 18 months) with no residual value at the end of the process.

Within that definition, we include the office supplies and consumables such as stationary (BL 4101), the computer software necessary (BL 4103) and the purchase of other materials falling within this category definition or of a value of less than US\$ 250.00 (BL 4121).

Non-expendable equipment (Budget Line 4201)

In this category, the project will consider computers and other equipment with a serviceable life expectancy longer than the project and a value of US\$ 250.00 or more. Given the parameters of the project, this budget category should remain limited.

Premises: Premises Costs (Budget Line 4301)

This category has only been included for the purpose of reflecting the costs of rental of premises as part of the government contribution.



Operation and maintenance of equipment: Equipment maintenance (Budget Line 5101)

This line is intended for repair of equipment, and other costs associated with their continued operation. This is not however a line to charge the supplies necessary for the use of equipment. For instance, the paper and toner for a photocopy machine should be charged under BL 4101 but the cost of the photocopier maintenance service and the lubricants for the machinery should be applied in BL 5101.

The amount to plan for depends on the nature and age of equipment. With new equipment a minimal amount can be programmed depending on the nature of the guarantee covering the product. Higher amounts may be necessary for older equipment. There is no 'rule of thumb' for applying these costs and estimates must take into consideration other experiences before being finalized.

It is expected that the costs involved with operations and maintenance will be borne by the host government/institution.

Publication and outreach materials (Budget Lines 5201)

This line is intended for all the reports and documents produced by the project as part of its development activities included outreach materials and printing of the draft Biosafety frameworks.

Reporting costs (Budget Lines 5220)

This line concerns the reporting by the project of its activities to UNEP/GEF, where these costs involve activities beyond the normal functions of the project staff. It is important to plan for the costs appropriately. However, it is expected that the costs of project reporting will be kept to a minimum, as they are generally absorbed by the normal use of project staff resources (charged elsewhere) or because they constitute an item of government contribution.

Sundry: Communications costs (Budget Line 5301)

This line is used to charge telephone, fax, telex, Internet access, email, and mail costs.

Evaluation: Audit of final accounts (Budget Line 5501)

Evaluation of project activities is an important task and is part and parcel of the accountability of projects to donors and stakeholders. As in the case of project reporting, UNEP has various requirements, which will be communicated under separate notes.

However a specific responsibility of the host government is to undertake an external audit of final accounts of the project as part of the overall evaluation effort. The cost for this audit would be expected to be a government contribution to the project budget.

4.1 The Logframe

The different steps in the project management cycle can be linked together systematically through a so-called *logical framework analysis* or "*logframe*", which provides an *analytical tool* for planning, design and management of projects. This systematic approach helps to include factors essential for the success of a project in preparation and implementation, and facilitates timely management decisions.

The logframe is an *analytical tool* to assist in the planning, design and management of projects. It is a systematic way of identifying the elements of a project and the linkages between them to provide a logical, concise and objective analysis of the project design. This systematic and logical approach is useful at all stages of the project management cycle: identification, appraisal, design, monitoring and evaluation. Its primary purpose is to promote a planning approach that focuses on achievement of purpose rather than on inputs and outputs.

The logframe *thought process* used in the design of a project. The result of this thought process is the *logframe matrix*, a convenient way of setting out the design elements of a project. The logframe is a dynamic document that should be reviewed and revised in light of experience during project implementation; it should not be used as a blueprint to be adhered to at all costs.



The result of the logical framework analysis is usually presented as a *matrix* of four rows and five columns, which provides a summary of the project design (Figure 6). This describes the project components², outlines how the project may be monitored, describes the risks and constraints, and suggests how these are to be managed.

- The first column, the narrative summary, records the hierarchy of goal, objectives, outputs, and activities: i.e., the *why, what and how*.
- The second is a statement of *what indicators* can be used to measure the achievement of the goal, objectives, outputs, and activities.
- The third column states *how* these are to be measured.
- The fourth column identifies the *risks and constraints* under which the project will be operating.
- The final and fifth column describes how these risks and constraints will be *managed* or taken into account in the design of the project.

The Logical Framework (logframe)

Summary	Indicators	Means of verification	Risks and constraints	Risk management
GOAL: The broader (national, local or programme level) goal to which the project contributes	Measures of achievement of the goal. These would be used during evaluation.	Sources of information (national statistics) Methods used.	Risks and constraints affecting the goal objective linkage, <i>including risks and constraints outside control of the project</i>	The specific components and strategies that are within control of the project <i>and those that are outside the control of the project.</i>
OBJECTIVES: The primary purposes of the project - a sustainable base for lasting benefits for target groups should be the ultimate aim. The objective should specify a time for achievement	Conditions at the end of the project indicating that the objectives have been achieved. These would be used for evaluation, ie end of project status	Sources of information (project data, evaluation) Methods used	Risks and constraints affecting the objective-output linkages.	The project specific outputs and activities that will help to address the risks/constraints identified
OUTPUTS: The direct measurable results of the project. The combination of outputs will help achieve the objectives.	The magnitude and quality of the outputs. These would be used for review and evaluation.	Sources of information (project data, review) Methods used	Risks and constraints affecting the output- activity linkage	The project specific activities that will address the risks and constraints identified.
ACTIVITIES: The actions carried out to implement the project (This could include inputs, timing and responsibility)	Implementation targets - type and quantity. These will be used for monitoring	Sources of information (project data,) Monitoring methods used	Risks and constraints affecting the successful completion of the project activities	These should either be addressed by other activities or by the way in which activities are carried out.

² A project component consists of a number of activities and outputs leading to a single objective. Components can be identified at either the output or objective level.



5. Protocol requirements

In July 2001 an Open-ended Meeting of Experts on Capacity-Building for the Implementation of the Biosafety Protocol was convened in Havana, Cuba. In that meeting an *implementation toolkit* was discussed and included in the documentation of the Second Meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP2), held in Nairobi, Kenya on 1-5 October 2001.

As an initial checklist of obligations found in the Cartagena Protocol we are attaching the *implementation toolkit* to this document. The attached section is extracted by the ICCP document UNEP/CBD/ICCP/2/10, pages 29-33 available on Internet at the CBD web site at the following URL:

<http://www.biodiv.org/biosafety/mtg-iccp-02.asp>

This implementation toolkit provides a compilation, as a checklist, of obligations found in the Cartagena Protocol on Biosafety. These obligations are organized in the following categories:

- Administrative tasks (initial and future)
- Legal requirements and/or undertakings
- Procedural requirements (AIA and Article 11)



I. Administrative tasks

Initial actions			
	Tasks	Article	✓
1.	Designate one national authority responsible for liaison with the Secretariat and provide name/address to Secretariat.	19(1),(2)	
2.	Designate one or more competent authorities responsible for performing administrative functions under the Protocol and provide name(s)/address(es) to the Secretariat. If more than one, indicate the types of LMOs for which each competent authority is responsible.	19(1),(2)	
3.	Provide to the Biosafety Clearing House: - any relevant existing laws, regulations or guidelines, including those applicable to the approval of LMO-FFPs; and - any bilateral, regional or multilateral agreements or arrangements.	20(3)(a)-(b), 11(5), 14(2)	
4.	Specify to the Biosafety Clearing House cases in which import may take place at the same time as the movement is notified.	13(1)(a)	
5.	Specify to the Biosafety Clearing House imports of LMOs exempted from the AIA procedures.	13(1)(b)	
6.	Notify the Biosafety Clearing House if domestic regulations shall apply with respect to specific imports.	14(4)	
7.	Provide the Biosafety Clearing House with a point of contact for receiving information from other States on unintentional transboundary movements in accordance with Article 17.	17(2)	
8.	Notify the Secretariat if there is a lack of access to the Biosafety Clearing House and hard copies of notifications to the Clearing House should be provided.	(e.g., 11(1))	
Follow-up actions			
9.	Provide to the Biosafety Clearing House: - Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Art. 15; - Final decisions concerning the import or release of LMOs; and - Article 33 reports.	20(3)(c)-(e)	
10.	Make available to the Biosafety Clearing House information concerning cases of illegal transboundary movements.	25(3)	
11.	Monitor the implementation of obligations under the Protocol and submit to the Secretariat periodic reports at intervals to be determined.	33	
12.	Notify the Biosafety Clearing-House of any relevant changes to the information provided under part I above.		



II. Legal requirements and/or undertakings

	Tasks	Article	✓
1.	Ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.	2(2)	
2.	Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for LMOs that may be exported as LMO-FFPs.	8(2) 11(2)	
3.	Ensure that any domestic regulatory framework used in place of the AIA procedures is consistent with the Protocol.	9(3)	
4.	Ensure that AIA decisions are taken in accordance with Article 15.	10(1)	
5.	Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.	15(1),(2)	
6.	Establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.	16(1)	
7.	Take appropriate measures to prevent the unintentional transboundary movements of LMOs, including measures such as requiring a risk assessment prior to the first release of an LMO.	16(3)	
8.	Endeavor to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.	16(4)	
9.	Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing House, and, where appropriate, relevant international organizations, when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of and LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.	17(1)	
10.	Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.	18(1)	
11.	Take measures to require that documentation accompanying LMO-FFPs - clearly identifies that they "may contain" LMOs and are not intended for intentional introduction into the environment; and - provides a contact point for further information.	18(2)(a)	



12.	Take measures to require that documentation accompanying LMOs destined for contained use: - Clearly identifies them as LMOs; - Specifies any requirements for their safe handling, storage, transport and use; - Provides a contact point for further information; and - Provides the name and address of individuals or institutions to which they are consigned.	18(2)(b)	
13.	Take measures to require that documentation accompanying LMOs that are intended for intentional introduction in the environment and any other LMOs within the scope of the Protocol: - Clearly identifies them as LMOs - Specifies the identify and relevant traits and/or characteristics; - Provides any requirements for the safe handling, storage, transport and use; - Provides a contact point for further information; - Provides, as appropriate, the name and address of the importer and exporter; and - Contains a declaration that the movement is in conformity with the requirements of the Protocol.	18(2)(c)	
14.	Provide for the designation of confidential information by notifiers, subject to the exclusions set forth in Article 21(6).	21(1),(6)	
15.	Ensure consultation with notifiers and review of decisions in the event of disagreement regarding claims of confidentiality.	21(2)	
16.	Ensure the protection of agreed-upon confidential information and information claimed as confidential where a notification is withdrawn.	21(3),(5)	
17.	Ensure that confidential information is not used for commercial purposes without the written consent of the notifier.	21(4)	
18.	Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs, taking also into account risks to human health.	23(1)(a)	
19.	Endeavor to ensure that public awareness and education encompass access to information on LMOs identified in accordance with the Protocol that may be imported.	23(1)(b)	
20.	In accordance with relevant domestic laws, consult with the public in decision making under the Protocol, while respecting confidential information.	23(2)	
21.	Endeavor to inform the public about the means of public access to the Biosafety Clearing House.	23(3)	
22.	Adopt appropriate measures aimed at preventing and, if appropriate, penalizing transboundary movements in contravention of domestic measures to implement the Protocol.	25(1)	
23.	Dispose, at its expense, LMOs that have been the subject of an illegal transboundary movement through repatriation or destruction, as appropriate, upon request by an affected Party.	25(2)	



III. Procedural requirements: advanced informed agreement

	Tasks	Article	✓
1.	Provide written acknowledgement of receipt of notification to notifier within 90 days, including:		
	- Date of receipt of notification;	9(2)(a)	
	- Whether notification meets requirements of Annex I;	9(2)(b)	
	- That the import may proceed only with written consent and whether to proceed in accordance with the domestic regulatory framework or in accordance with Article 10; OR	10(2)(a), 9(2)(c)	
	- Whether the import may proceed after 90 days without further written consent.	10(2)(b)	
2.	Communicate in writing to the notifier, within 270 days of receipt of notification:	10(3)(a)-(d)	
	- Approval of the import, with or without conditions;		
	- Prohibition of the import;		
	- A request for additional relevant information in accordance with domestic regulatory framework or Annex I; or		
	- Extension of the 270 day period by a defined period of time; AND		
	Except where approval is unconditional, the reasons for the decision, including the reasons for the request for additional information or for an extension of time.	10(4)	
3.	Provide in writing to the Biosafety Clearing House the decision communicated to the notifier.	10(3)	
4.	Respond in writing within 90 days to a request by an Exporting Party for a review of a decision under Article 10 where there has been a change in circumstances or additional relevant scientific or technical information has been made available, providing the reasons for the decision upon review.	12(2),(3)	

IV. Procedural requirements: living modified organisms for direct use as food, feed or for processing

	Tasks	Article	✓
1.	Upon making a final decision regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, inform the Biosafety Clearing House within 15 days of making that decision, including the information listed in Annex II.	11(1)	
2.	Except in the case of field trials, provide hard copies of the final decision to the National Focal Point of Parties that have notified the Secretariat in advance that they do not have access to the Biosafety Clearing House.	11(1)	
3.	Provide additional information contained in paragraph (b) of Annex II about the decision to any Party that requests it.	11(3)	
4.	In response to the posting of a decision by another Party, decide whether that LMO-FFP may be imported:	11(4),(6)	
	- either as approved under the domestic regulatory framework consistent with the Protocol; OR		
	- in the absence of a regulatory framework, on the basis of a risk assessment in accordance with Annex III within no more than 270 days. In this case, a declaration must be made to the Biosafety Clearing-House.		

