



Global Environment Facility

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January 6, 2003

Dear Council Member,

The World Bank, as the Implementing Agency for the project, ***Colombia: Capacity Building for the Implementation of the Cartagena Protocol***, has submitted the attached proposed project document for CEO endorsement prior to final approval of the project document in accordance with the World Bank procedures.

The Secretariat has reviewed the project document. It is consistent with the proposal approved by the Council in October 2002 and the proposed project remains consistent with the Instrument and GEF policies and procedures. The attached explanation prepared by the World Bank satisfactorily details how Council's comments and those of the STAP have been addressed. I am, therefore, endorsing the project document.

We have today posted the proposed project document on the GEF website at www.gefweb.org. If you do not have access to the Web, you may request the local field office of the World Bank or UNDP to download the document for you. Alternatively, you may request a copy of the document from the Secretariat. If you make such a request, please confirm for us your current mailing address.

Sincerely,

for Mohamed T. El-Ashry
Chief Executive Officer and Chairman

cc: Alternate, Implementing Agencies, STAP

OFFICE MEMORANDUM

DATE: November 26, 2002

TO: Ken King, Assistant CEO, GEFSEC
Att.: GEF PROGRAM COORDINATION

FROM: Lars Vidaeus, GEF Executive Coordinator 

EXTENSION: 3-4188

SUBJECT: **Colombia: Capacity Building for the Implementation of the Cartagena Protocol on Biosafety in Colombia**
GEF Medium Size Project (MSP) for CEO Endorsement – Resubmission (if required)

Please find attached the project document for the above-mentioned project for your final review and endorsement. The German Council Member's comments have been addressed as follows:

Comment. The proposal recognizes that Biosafety is a cross-cutting issue and does not belong to the responsibility of one single ministry. The Interministerial Commission, referred to under 12.2 GEF Alternative, does not appear in the project components. Thus, within the proposal, no concrete measure is planned that would enhance inter-ministerial cooperation (with the exception of the Intersectoral Council, but this has only supervising functions and meets not more than twice a year).

Response. *The Interministerial Commission is not included as a specific component because the development of it's capacity will be a product of project activities particularly under Component 1. The Intersectoral Council has more than supervisory functions. It's role as detailed in Section 11, Institutional Arrangements, is to develop operational plans, approve budgets, and monitor the project's progress. The IC has broad representation including all relevant ministries (Health, Environment, Trade, etc.). Finally, the National Biosafety Council will also be created under the project and will advise the government on the adoption of policies, regulations and the unified decisions on biosafety. It will be comprised of three Technical Committees with expertise in environment, health and agriculture. Each of these bodies is multi-sectoral in representation and through the project's activities opportunities for improved coordination will be enhanced.*

Comment. The first measure mentioned under Component 1 (legislative framework) are regional workshops. This does not reflect the fact that a legislative framework is a national duty! There is nothing to say against inviting international/regional experts for framework development, but the decisions have to be taken within Colombia. Regional workshops are more likely to serve training or best practice dissemination.

Response. *The word “regional” in this context applies to the regions of Colombia not the region of Latin America. The regional approach is adopted so as to enhance the participation of various civic group in developing the legislative framework.*

Comment. Under component 4 (research) special attention has to be given to possible overlaps with the BMZ funded research project, mentioned in this same section (no double funding!).

Response. *Thanks for bringing this to our attention. The Task Manager will communicate this information to the implementing agency and will follow up with formal contacts.*

Comment. There is another point of contact with German activities in Colombia: The Ministry of Environment has submitted a proposal for education and communication in biosafety issues to the GTZ sectoral project Implementing *the Biodiversity Convention* within the German Biosafety Capacity Building Initiative. This proposal is not mentioned in the GEF proposal. Apparently, there are no overlaps between the two respective projects (the one to GTZ deals with school curricula, multipliers and public education, not with the training of experts), but there has to be kept an eye on, when it comes to the implementation of the two projects.

Response. *You have correctly pointed out that there are no overlaps between the GTZ and the GEF project. However the Task Manager will again establish contacts with this initiative.*

Please let me know if you require any additional information to complete your review of the project document. Thanks.

cc: **Mmes./Messrs.:** K. Shepardson, T. Bradley, M. Isaac, M. Serra, (LCSES); K. MacKinnon, S. Wedderburn, R. Khanna, D. Aryal (ENV); ENVGC ISC, IRIS1

PROJECT BRIEF

1. IDENTIFIERS:

PROJECT NUMBER	P077171
PROJECT NAME	Capacity Building for Implementation of the Cartagena Protocol
DURATION	3 years
IMPLEMENTING AGENCY	THE WORLD BANK
EXECUTING AGENCY	ALEXANDER VON HUMBOLDT INSTITUTE
REQUESTING COUNTRY	Colombia
ELIGIBILITY	Cartagena Protocol signed May 24, 2000
GEF FOCAL AREA	Biodiversity
GEF PROGRAMMING FRAMEWORK	ENABLING ACTIVITY

2. SUMMARY:

The project will help consolidate Colombia's national capacity for the implementation of the Cartagena Protocol on Biosafety. The Government of Colombia has placed a high priority on developing a framework as reflected in its National Development Plan by promoting research on biodiversity friendly goods, including supply, demand, barriers and opportunities; and, promoting such goods and coordination of the implementation of the Biosafety Clearing House (BCH).

Specifically, the project will develop national capacities in biosafety required to: (i) strengthen the legislative framework and operational mechanisms for biosafety management in Colombia; (ii) build capacity and establish an operational system for risk assessment and monitoring; (iii) establish the biosafety database system and Biosafety Clearinghouse Mechanism; (iv) support centers of excellence and a network for research, risk assessment, and monitoring; and (v) establish the Project Coordinating Unit (PCU). The development of national capacities in these areas will consolidate the national framework for biosafety management. The project builds on the experience accrued in Colombia on public health, plant and animal health inspection services, biodiversity conservation efforts and promotes cross-sector synergies.

Colombia had expressed interest in receiving support in the first phase through UNEP, but during interagency meetings with the implementing agencies and GEF it was agreed that Colombia was too advanced in biosafety capacity to qualify for the first stage, and should proceed directly to the second stage. It was further agreed that the World Bank would be the implementing agency for such support, since it has and continues to provide active support to biodiversity conservation and agricultural research through its lending program. The agreement also specified that UNIDO and UNEP would be secondary for coordinating the proposal. The project design has benefited from technical inputs provided by the local GEF committee in Colombia comprised of representatives of the Ministry of Environment, the Office of International Cooperation of the Ministry of Interior, the UNDP and the World Bank. These inputs were formally channeled to the GEF Focal Point, the Ministry of Environment.

3. COSTS AND FINANCING (MILLION US\$):

GEF:	-Project	US\$ 0.975 million
	- PDF A:	US\$ 0.025 million

	Subtotal GEF:	US\$ 1,000 million
Co-	:	
FINANCING:	-Gov. of Colombia	US\$ 2,478,123 million (937,186 incremental, 1,531,237 Baseline,
	-IBRD:	9,700 PDF)
		US\$ 1,000 million
	TOTAL PROJECT COST (w/ PDF A):	US\$ 4,478,123 million
	TOTAL PROJECT COST (w/o PDF A):	US\$ 4,443,423 million

4. OPERATIONAL FOCAL POINT ENDORSEMENT

BLOCK A: The project was given the official support of the Vice-Minister of the Environment, Ms Claudia Martinez Zuleta, Letter of support October 23, 2000.

MSP Brief: The Project was endorsed by Colombia's Minister of the Environment. Correspondence from Mr. Juan Mayr Maldonado to Karin Shepardson, July 19, 2002.

5. IMPLEMENTING AGENCY CONTACT

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6. LIST OF ACRONYMS

BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CIAT	International Centre of Tropical Agriculture
CTN	National Technical Committee
COD	Centre of Origin and Diversity
COLCIENCIAS	The Colombian Science Research Council
CP	Cartagena Protocol
FAO	Food and Agriculture Organisation
GEF	Global Environment Facility
IavH	The Alexander von Humboldt Institute
ICA	Institute for Colombian Agriculture
ICCP	Intergovernmental Committee Cartagena Protocol
INCOTC	Colombian Institute for Technical Norms
INVIMA	Food and Drug Inspection Institute
LMO	Living Modified Organism
MINAMBIENTE	Ministry of Environment
NBF	National Biosafety Framework
NAFTA	North American Free Trade Agreement
NGO	Non Governmental Organisation
OAS	Organization of American States
PCU	Project Coordinating Unit
PRONATA	National Agricultural Technology Project
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organisation
WWF	World Wildlife Fund
WTO	World Trade Organization

7. BACKGROUND AND PROJECT CONTEXT:

7.1 National Development Plan

Colombia's National Development Plan promotes a medium and long-term development agenda, emphasising the need to balance economic, social and environmental objectives and encouraging the active involvement of civil society in environmental management.

Colombia was one of the leading countries in formulating the Cartagena Protocol and is one of the first to sign and ratify the Protocol. Colombia is also a major center of biodiversity and home to many local and native species of agricultural crops. Recognizing this, the national development plan gives priority to development of capacity in Biosafety and related research on biodiversity. While a basic capacity to regulate Living Modified Organisms (LMOs) has been developed in some organizations, such as the Institute for Colombian Agriculture (ICA), deeper and wider capacity building remains a high priority, especially in a rapidly changing field such as biosafety. Members of the National Technical Committee on Biosafety (CTN) which was established as an advisory body on the applications of LMOs for importation, production, testing, marketing and commercial releases have received training from the International Center of Tropical Agriculture (CIAT). However, other key ministries such as environment, health and external trade have yet to develop a minimum capacity to analyze and assess risks for decision making. This is especially true for environmental impact assessment, food safety and allergenicity related to released LMOs, or commercial imports for food use.

The Government of Colombia has also recognized the need to establish an inter-ministerial mechanism to formulate national policies and coordinate decision making on biosafety issues that cuts across sectoral boundaries. Additionally, current regulations only cover LMOs for agricultural use intended for release into the environment and Regulations on other LMOs and commercial imports of LMOs for food and feed are still being established.

7.1.2 National Focal Point on Biosafety

The Ministry of External Relations is the National Focal Point for Biosafety in Colombia. The Ministry played a key role in the negotiations leading up to the signing and ratification of the Cartagena Protocol. In November 1998, the CTN was created to advise the Director of ICA on applications related to introduction, use and commercialisation of LMOs. In June, 2001, the Ministers of the Environment, Agriculture and Rural Development, International Trade and Health established a working group made up of representatives of their respective Ministries along with ICA and the Alexander von Humboldt Institute (IAvH). The working group developed an Action Plan to promote a coordinated approach to Biosafety in Colombia. A key element of the Action Plan was the development of a mechanism to facilitate an inter-sectoral approach to Biosafety and policy formulation and decision making at the national level. In a highly participatory fashion the working group has played a key role in the preparation of the proposed Medium Sized Project (MSP).

7.2 Biosafety Framework in Colombia

7.2 Government Commitment: The Government of Colombia has shown its commitment to Biosafety issues by implementing several measures since 1991. Four principal facets of the Biosafety framework are detailed below: institutional, legal, environmental and public information.

7.21 Institutional Context

The Government of Colombia's institutional capacity to address biosafety issues has gradually been developed since 1991, with several national agencies contributing to Biosafety analysis based on their respective mandates. These include: The Ministry of Environment (MINAMBIENTE), Ministry of Agriculture and Rural Development, ICA, and the Ministry of Health. In addition, the Ministry of International Trade, the Ministry of External Relations, the Colombian Science Research Council (COLCIENCIAS), Food and Drug Inspection Institute (INVIMA), and the Alexander von Humboldt Institute are also involved in developing policies and research related to Biosafety. MINAMBIENTE played an important role in the negotiations which led to the Cartagena Protocol and is the key national level institution charged with implementing the Convention on Biodiversity. In the context of biosafety, MINAMBIENTE has the responsibility for regulating the importation and trade in genetic material and for insuring that Colombia receives appropriate compensation.

The Ministry of Agriculture and Rural Development under the Department for Technological Development and Animal and Plant Health, has a specific mission to develop policies in science and technology applied to the agriculture sector, including policies related to biotechnology.

The Institute for Colombian Agriculture (ICA), a dependency of the Ministry of Agriculture and Rural Development, is charged with protecting crop and livestock production systems and health and minimizing food and environmental risks related to agriculture. ICA regulates crop variety testing and releases, including the importation, testing and commercial release of transgenic materials, commonly known as Living Genetically Modified Organisms (LMOs).

The Ministry of International Trade has an important role in setting trade policy of Colombia and its relationship with the WTO. In accordance with the relevant international agreements and especially the Cartagena Protocol, in which Colombia is a signatory, the Ministry regulates the international trade of biotechnology products for feed food and processing (commodities).

The Ministry of Health is responsible for regulating pharmaceuticals and in general all products for human consumption. INVIMA regulates, inspects, controls and licenses the above mentioned products.

The Institute for Research on Biological Resources, Alexander von Humboldt (IavH) promotes, coordinates and carries out research that contributes to improving knowledge, conservation and sustainable use of biodiversity in Colombia. The IavH has developed research activities in four main areas: biodiversity inventories, conservation, use and evaluation of genetic resources.

Finally, as in all countries, there is a strong need to increase public dialogue and awareness with respect to LMOs. Stakeholders that represent the interests of consumers, producers, and environmentalists must be more effectively involved in policy formulation and risk and benefit assessment of LMOs.

7.2.2 Legal Context.

Colombia is a signatory to the Convention on Biological Biodiversity (CBD), which was ratified by Congress on Nov 28th, 1994 (Law 165/94). Under the CBD, through its Article 8, GOC is committed to establish or maintain the means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology and that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human

health. On May 24th, 2000, Colombia signed the Cartagena Protocol, which was recently ratified in May 2002 .

The legal framework for natural resources conservation and environmental protection can be found in a number of National laws going back as far as 1974 (Law 2811). The development of these laws and policies is directly related to different sectoral demands including the conservation and safe use of genetic resources. The new National Constitution issued in 1991 (Articles 80 and 81) mandates that the government regulate the exportation of genetic resources.

Law 99 which established Colombia's National Environmental System requires that the environmental impact be assessed when activities are believed to have a potential impact on the natural environment. The scope of this law could include the environmental impact of the introduction of LMOs into the agricultural production system as well as the effects of exotic or genetically modified plants in natural ecosystems.

ICA has issued two "agreements" (013/98 and 004/ 02) and issued "resolutions" (No. 3492 and No. 2935) that outline procedures for introduction, research, production, release, and marketing of LMOs for agricultural and livestock use. The agreements signed by the Minister of Agriculture as a head of the Board of Directors of ICA established the National Technical Council (CTN), as an advisory body on the applications of LMOs for importation, production, testing, marketing and commercial releases.

The Ministry of Health issued Decree No. 977 in 1998 that establish the Codex Food National Committee. This Committee is made up of representatives of the relevant ministries (Economic Development, Health, International Trade, Agriculture and Rural Development), ICA, National Institute for Drugs and Foods Safety (INVIMA), and the Colombian Institute of Technical Norms (INCOTC). The committee advises the national government on policy development related to food safety and security and represents Colombia in its participation in the FAO/WHO Codex Food Commission.

7.2.3 Environmental Context

Colombia is part of the Andean region and center of origin and domestication of numerous plants that have provided food and other products including: Potato (*Solanum tuberosum*), Sweet Potato (*Ipomoea batatas*), Maize (*Zea mays*), Tomato (*Lycopersicon esculentum*), Beans (*Phaseolus vulgaris*), Cassava (*Manihot esculenta*), Peanut (*Arachis hypogea*), Pineapple (*Ananas comosus*), Cocoa (*Theobroma cacao*), Peppers (*Capsicum annum*, *C. pubescens* & *C. frutescens*), Papaya (*Carica papaya*), la Mora de Castilla (*Rubus Glaucus*), Cotton (*Gossypium hirsutum* & *G. barbadense*) and Tobacco (*Nicotiana tabacum*).¹

The full nutritional and medicinal value of many others plants of Latin American origin has not yet been determined. This include grains such as Quinoa (*Chenopodium quinoa*); Kañiwa (*Chenopodium pallidicaule*) and Amaranthus (*Amaranthus caudatus*). Tubers such as Bitter Potato (*Solanum juzepczukii*); Oca or Ibia (*Oxalis tuberosa*); Ulluco (*Ullucus tuberosus*); Mashwa or Cubio (*Tropaeolum tuberosum*). Roots such as Arracacha (*Arracacia xanthorrhiza*); Achira (*Canna edulis*); Jicama (*Pachyrhizus tuberosus*); Yacón (*Polymnia sonchifolia*); Mauca or Chago (*Mirabilis expansa*); Maca (*Lepidium meyenii*) and Ajipa (*Pachyrhizus ahipa*). Legumes such as

¹ Artunduaga R, 2000. Biosafety Regulations related to Transgenic Plants in latin American and the Caribbean Region: the Andean countries as a model. .6th International Symposium on the Biosafety. July 2000, Saskatoon Canada.

Cacha (*Phaseolus polyanthus*); Tarwi (*Lupinus mutabilis*); Torta (*Phaseolus lunatus*); Pajuro (*Eritrina edulis*) and Pacay (*Inga feuillei*). Vegetables such as: Zapallo (*Cucúrbita máxima*) and Achokcha (*Cyclanthera pedata*). Fruits such as: Pitaya (*Acanthocereus sp*); Pepino (*Solanun variegatum*); Uchuva (*Physalis peruviana*); Tomato tree (*Solanum betacea*); Granadilla(*Passiflora ligularis*); Curuba (*Passiflora mollisima*); curuba de Indio (*Passiflora mixta*); Tin-Tin (*Passiflora pinnastistipula*); Curuba Antioqueña (*Passiflora antioquiensis*); Badea (*Passiflora quadrangularis*); Cherimoya (*Annona cherimolia*); and Ciruela de Fraile (*Bunchosia armeniaca*).²

The potential contribution of biotechnology to sustainable agriculture is expected to be high, but the introduction of transgenic varieties in tropical ecosystems deserves careful oversight and monitoring. This issue is of particular importance in the Andean region due to its high level of genetic diversity for a large number of species that are mentioned above and the concern over the likelihood of genes spreading from transgenic crops to wild relatives and the potential impacts on crop genetic diversity. Risk assessment related to the natural environment is a necessary element of any biosafety program and is a key element of the proposed GEF/GOC project.

Progress in biotechnology research has been particularly rapid in some of the most valuable crops of the region. Scientists hope that the development of transgenic plants will help to alleviate both the heavy use of pesticides and the susceptibility of traditional cultivars to a number of pest and a biotic stresses. Projected results to 2001 based on the use of LMOs maize, soybean and cotton from 1997 to 2000 in the USA (Kline & Co, 2000), indicate a reduction in application of 22% for herbicide and 70% for insecticides. Similarly in China, data from the last seven years of commercial use of insect resistant Bt cotton, shows a considerable decrease in child mortality that has been associated with insecticide applications in the non-transgenic crop.

7.2.4 Public Information

Over the last few years in order to increase public awareness on LMOs and their related biosafety issues, ICA has organized 25 workshops directed to stakeholders, policy makers, the scientific community, and the civil society. In this context, the GEF project broaden stakeholder participation and public information by including key representatives of each of these sectors in the capacity building component through courses and publications, and through the dissemination of information by the BCH mechanism.

7.3 Current Situation (Base-line Capacity and Identified Gaps):

7.3.1 Institutional

Colombia was one of the leading countries in formulating the Cartagena Protocol and was one of the first to sign the Protocol, which it ratified in May 2002. Colombia is also a major center of origin and diversification of several agricultural crops. The National Development Plan identifies biosafety research and capacity building as an important national priority. Although a good start has been made towards developing a regulatory framework for LMOs and initial steps have been undertaken for its implementation in an integrative manner (including the health and environment sectors), the process has encountered obstacles due to the lack of an inter-sectoral regulatory framework, uneven biosafety knowledge among members of the future Biosafety Council, the lack of a well designed biosafety information system, and the limited knowledge on plant-environment interaction under tropical ecosystems. The expected outcomes of the present GEF project is an important step for closing these gaps and builds on current government efforts.

² Artunduaga R. 2002. The Importance of using Biotechnology for the Tropical LAC Countries. .Agri-Net, April 2002. USA.

The members of the CTN have participated in a training course on LMO biosafety sponsored by the International Center for Tropical Agriculture (CIAT). However the environment, health and external trade ministries have yet to develop a minimum capacity to analyze and assess risks for decision making. This is especially true for food safety and allergenicity related to released LMOs, or commercial imports for food use.

In 1996, ICA established a Genetic Resources and Biosafety Unit which has worked on the conservation of plant and animal genetic resources for agriculture use and risk assessment and evaluation associated with requests for research and commercial release of LMOs. The current strength of its professional staff provides expertise in the areas of plant and animal genetics, animal nutrition, molecular biology, and crop production systems. Some of the staff have received international training on biosafety. However, ICA lacks technical capacity and infrastructure for the mass evaluation and monitoring of LMOs samples that may enter the market, a requirement of the Cartagena Protocol.

The Alexander von Humboldt Institute promotes, coordinates and conducts research on the conservation and sustainable use biodiversity. These activities include: organism biodiversity; research on conservation biology, and assessment of value added from the biodiversity. In the context of environmental biosafety, the interest of the IavH is directed at assessing potential impacts on non target organisms additional training is required to permit IavH staff to undertake assessments of LMOs-environmental interactions with special focus on the potential impacts of agriculture production systems on natural environments and to analyse opportunities for bioremediation.

INVIMA has the needed infrastructure and trained personnel for the evaluation of pharmaceutical and processed food products, to comply with its mandate for commercial regulation. In relation to food biosafety of LMO derived products, an increased capacity and updated infrastructure is needed to ensure mass evaluation and monitoring of LMO food samples for safe human consumption prior to their commercialisation.

The International Centre for Tropical Agriculture (CIAT) has a strong internationally recognized training and research capacity on agriculture biotechnology applied to tropical ecosystems, including its ongoing research agenda on environmental risk assessment, especially in the area of genetic dispersion and introgression into cultivated crops, land races, and wild/ weedy related species. CIAT's Science Park includes a number of Colombian institutions(the IAVH and COPORICA) which facilitate technology transfer to Colombian Institutions within the context of this project. Risk evaluation capacity can also be greatly enhanced by ready access to information from other countries in the region and elsewhere. Finally, as in all countries, there is strong need to increase public dialogue and awareness with respect to LMOs. Stakeholders that represent the interest of consumers, producers, and environmentalist, must be more effectively involved in policy formulation and risk and benefit assessment with respect to LMOs.

7.4 Barriers to fully Implement the Cartagena Protocol

A number of significant barriers that prevent the full implementation of the CP in Colombia have been identified and are described below:

7.4.1 Institutional, Legal, and Policy

Under the existing institutional framework, implementing the CP would prove to be difficult. Key institutions are under-funded, have inadequate infrastructure and lack trained staff. At the same time, the decision-making apparatus lacks sufficient inter-institutional communications and processes and reflects inadequate understanding of the impacts of those decisions. Capacity is also lacking in the area of monitoring and evaluation, including important laboratory analysis of LMOs. Institutional development is absolutely essential for meeting the challenges presented in the CP.

The current legal framework for biosafety is largely derived from existing, sector-specific legislation (especially environment, agriculture and health) that has been adjusted to encompass the commercial applications of transgenics through new standards. A broad-based national dialogue on biosafety is a necessary element for a comprehensive legal framework. As a megadiversity country, and in a commercial environment of trans-boundary movement of LMOs, Colombia has a global responsibility to design and implement a strong, unambiguous and effective legal framework. Under the baseline course of action, modifications to the legal framework will most likely continue. However in the absence of reliable and unbiased information, a wider national dialogue, and the evaluation of experiences in other megadiversity countries, continued fragmentation of the legal framework and a proliferation of sector-specific legislation is a likely product. Over time, this would tend to dilute Colombia's response capacity to the CP.

The proposed GEF project will implement activities aimed at overcoming these deficiencies and help to set in place an institutional framework for both research and policy making related to biosafety.

7.4.2 Human resources.

Colombia has a very small cadre of professionals with knowledge of safe production, use and handling of LMOs. Aside from private company laboratories and a handful of experts in the field, there is very little knowledge of the nature of LMOs, nor of methodologies to adequately measure their potential risks and benefits. This is especially true in small agricultural communities, as well as for animal and plant health inspection officials at important commercial points-of-entry. Human resource limitations are also a significant barrier to rural knowledge and capacity for managing LMOs. A key objective of the proposed GEF project will be to develop a minimum human resource capacity in order to meet the demands of the CP.

7.4.3 Technical and Information Barriers .

Colombia needs to develop a capacity for data management, *in situ* monitoring in reduced areas and established methodologies in the agriculture and health sectors for monitoring plant and animal populations. These require increased capacity for supervising trans-boundary movement of LMOs. A key objective of the proposed GEF project is to establish a network for evaluation, monitoring and research on biosafety, which will link the human resources developed in this project with the national technical capacity through strategic alliances. This network will make available to the national and international community information generated through the BCH mechanism proposed herein.

8. GEF ALTERNATIVE COURSE OF ACTION:

8.1 Project Objectives:

The **development objective** of the project is:

Colombia will be able to implement the basic objectives of the Cartagena Protocol, including the assessment, management and monitoring of the potential risks posed by transboundary movement of LMOs to the conservation and sustainable use of biodiversity, including human health risks. The major objectives for GEF support would be to improve capacity across ministries and among key stakeholders to analyze, inform, and make decisions to reduce potential risks related to LMOs, increase benefits to society, and protect biodiversity.

The immediate objective is:

Within three years, the country will build sufficient capacity to assess and manage risks associated with the trans-boundary movement of LMOs through the strengthening of the legal and regulatory frameworks, enhanced institutional capacity and effective communication strategies. Knowledge and methodologies on Biosafety will be shared and transferred through the establishment of sub-regional (Andean) training programs based in Colombia.

8.2 Project Strategy

The main activities of the project are focused on the identification, regulation and management of the risks derived from the trans-boundary release and utilisation of LMOs, that might present adverse risks to the conservation and sustainable use of biological diversity, taking also into account potential risks to human health. This national approach to capacity building contemplates risk assessment and management, monitoring and evaluation, legal and regulatory reform/strengthening, broad social participation and a dissemination strategy in the context of the Advanced Informed Agreement. GEF is requested to participate in strategic elements of this approach over the medium-term horizon (3 years) permitting the longer-term consolidation of the strategy. The GEF-financed portion of the project includes training and risk management components that will ensure sustainability and information exchange over the long-term. The project concentrates GEF funds in the areas of trans-boundary risk assessment and management as these are considered to be vital to the implementation of a large-scale communication campaign. Consolidated capacities in these two areas will also help detect additional gaps in the legal framework and will help fine tune possible strategies for its modification. GEF support will have a catalytic and consolidating effect on the national effort spearheaded by the Intersectoral Council (IC).

Strategic considerations for program design.

Design of this program for capacity development will recognize a number of strategic concerns:

- Biosafety is a rapidly changing field as more is learnt about the science and its interaction with biodiversity and consumer concerns. Any program will necessarily be one step in a continuous program of capacity development. The need is large and priorities for this program must be carefully identified.
- Biosafety is a highly technical area that requires considerable scientific skill. On the other hand, it also requires broad understanding and ready access to information from the public at large, especially producer and consumer groups.
- The issues of Biosafety and risk assessment are crosscutting and no single ministry or sector can have sole responsibility for decision making. For this reason, capacity development must be sustainable. This requires essential capacity building for personnel, infrastructure and equipment with major concentration on upgrading skills and knowledge of current staff through training and information sharing.

The anticipated activities and outcomes for each component are summarized below:

Component 1: *Strengthening the legislative framework and operational mechanisms for Biosafety management in Colombia*

**TOTAL COST US\$ 563,432 / BASELINE US\$116,200/ GEF US\$130,928/ GOC
US\$316,304**

With Colombia's ratification of the Cartagena Protocol on Biosafety through Law 740 in May 2002 it became imperative for the country to adopt a national legislative framework which regulates and harmonizes activities related to LMOs across different sectors and organizations. Co-financing resources would be used to carry out an in-depth evaluation of Colombia's current legal framework in the context of the Cartagena Protocol and make recommendations for a National Biosafety legislative and policy framework for the protection of human, animal and plant health, the environment and the socio-economic wellbeing of the population.

Considering that the Cartagena Protocol specifically applies to the transborder movement of LMOs, it is necessary to evaluate the existing regulatory instruments and develop others which will ensure an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity within the country. In preparation for the Protocol becoming effective, these instruments need to be developed as soon as possible.

Given the wide spectrum of biotechnology products (and their potential impacts) different sectoral institutions (environment, agriculture, health, trade, foreign relations and research establishments) have assumed responsibilities for specific segments. This calls for the creation of a high level interinstitutional mechanism that will advise the government on the adoption of policies, regulations and the unified decisions on biosafety. To this effect an important goal of the project will be to establish a National Biosafety Council (NBC)) comprised of three Technical Committees with expertise in environment, health and agriculture.

Although the NBC will be created by decree and consequently have an advisory role, it is expected that with the national biosafety law it will become a decision making body.

To ensure wide participation, two regional workshops will be organized with the aim of creating the legislative framework on Biosafety. The workshops will deal with different aspects as they refer to the legislative instrument such as the main principles, regulated activities, criteria and assessment processes, institutional framework, and procedures as they apply to the Protocol. The workshops will involve not only technical experts and government officials, but also key representatives of civil society (i.e. NGOs, consumer association, press release) to ensure a collective foundation for reaching a broad understanding and endorsement of priority biosafety issues. Guidelines on key aspects to be included in the information sharing mechanism, and on activities addressing risk assessment, monitoring, databases and research, would be clear spill-overs of this cross-sectoral approach. Such consultation with diverse stakeholders would be fundamental to implementation of this project. This is also reflected in the participation of government officials and civil society, along with the scientists in the training courses of Component 2.

Component 2. Capacity building and establishing an operational system for risk assessment and monitoring

TOTAL COST US\$ 247,660 / BASELINE US\$0.00 / GEF US\$156,000/ GOC US\$91,660

1) Training

Training is crucial part of the project. Along with the development of the regulatory system, experts will be trained to enforce the law and the provisions of the Cartagena Protocol on Biosafety. In particular, the first event will be a training of trainers in the following Ministries:

- Ministry of Environment: responsible for the environmental impact assessment, and focal point for the CBD and Biosafety Protocol activities;
- Ministry of Agriculture: responsible for the field trials and laboratory risk assessments, it will co-ordinate risk management of agricultural LMOs and their products;
- Ministry of International Trade: establishes trade policy and relationship with WTO;
- Ministry of Health: responsible for food safety, hence for the safety of LMO products used in food processing and production;
- COLCIENCIAS: responsible for science issues and will provide advice on scientific work in this area.

The following training activities are planned:

- a. Two training courses for 60 trainers from the Ministries of Agriculture and Rural Development, Health, Environment, International Trade, policy makers, NGOs, media, consumer and producer groups. This course will specifically focus on contained, deliberate release and commercial use of LMOs. This course would emphasise biosafety issues from an interdisciplinary perspective, including general technical background for risk assessment and management of LMOs, LMOs under agriculture settings, and interactions of LMOs with non-target organisms. Equal attention will be given to molecular biology, organism biology, population biology and ecology under an environmental context, as well as to health factors .
- b. A workshop for 60 representatives of government, media, NGOs, consumer groups and scientific community on socio-economic and legal aspects related to LMOs. Special attention will be given to socio-economic impacts, trans-boundary movement of LMOs, and the Cartagena Protocol.
- c. Five courses of three-to-twelve-day each for a total of 115 representatives of government dealing with risk assessment, risk management, and research, and selected scientists from the centers of excellence network (Component 4). These courses will be of higher knowledge level and technical specialisation on interdisciplinary biosafety issues, including general technical background for LMO risk assessment and management, LMOs under agriculture settings, and LMOs interactions with the environment and health. The two model crops (proposed for research in Component 4) will be used as case studies for discussion of *in itinere* biosafety strategies (ex-ante and ex post).
- d. Besides these training courses and workshops, 10 short term (3-month each) and 6 long term (6-month each) visiting scientists exchanges will be conducted to allow more specialised training of selected technical personnel engaged on risk assessment, risk management, and research. At least four short term and two long term (about 38%) of these visiting scientist exchanges will be used to strength collaboration between parties involved in the research

proposals on potato and rice described in Component 4. In this way, part of the training capacity will be built upon doing actual real assessment.

The training events will include lectures by foreign experts, case studies and experience sharing between the participants.

2) Risk Assessment

This project will take into account risk assessment and risk management procedures as identified in Articles 15 and 16 of the Protocol, including any scientific skills that might be required. This will allow Colombia to: (i) Assess, manage and control risks and adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, including risks to human health; (ii) Ensure adequate protection of the environment; (iii) Minimize the risks posed to their ability to trade with other countries; and (iv) Provide mechanisms for technology transfer and benefit sharing. A quarterly news letter, training materials on specific areas of biosafety including technical manuals and press-releases will be produced and published. Additionally, other countries of the Andean Region will have access to this information.

Botanical files will also be compiled in order to collect the relevant and validated data concerning host plants that might be applied in genetic modification experiments. The botanical files will help in creating a common base of information for all the involved stakeholders for the following reasons:

- Both, old and recent floristic data, will be included thus creating a starting point for monitoring activities;
- Original references to the data will be included in order to track the history of the information.

The collected data will support competent decision-making and advisory bodies in deciding concrete cases of notifications or ongoing monitoring of approved LMOs.

In order to perform risk assessments and monitoring in compliance with the requirements on transboundary movements and labelling as per LMOs Act, this project proposes to establish a network of laboratories which will promote strategic alliances within the national research capacity according to needs .

Component 3. Establishing the biosafety database system and Biosafety Clearing-House Mechanism in Colombia

**TOTAL COST US\$ 353,085 / BASELINE US\$28,400 / GEF US\$131,322/
GOC US\$193,363**

Information sharing and dissemination will rely on a data base network and web page, developed according to the recommendations of the “Note by the Bureau of the ICCP on technical issues associated with the implementation of the Pilot Phase of the Biosafety Clearing-House” and its Annexes 2 and 3.

An information database and network will be set up and contain registers, dossiers, trial data and other related information required by the Cartagena Protocol on Biosafety. The database will be

accessible by all government organizations, NGOs, other interested parties and the public will have access to the database through the website as follows:

- NGOs, journalists and any interested parties can access the unprotected information of the database;
- The general public or any interested party can get general information on biosafety-related activities and issues just by accessing the web site.

The database will have an additional regional component containing relevant information on LAC countries or a direct link to their websites and other information sources. As part of the information display, the database will include information generated by the training (Component 2) and the centers of excellence (Component 4) components of this project. The proceedings of the courses and biosafety guides will be available for consultation by other countries in LAC. English versions could be prepared in a second phase to make those documents also available to other tropical countries world-wide. Research results generated from the two pilot research projects on gene flow of potato and rice proposed in Component 4 of this project, will be posted for consultation. In this context, the BCH mechanism will be used to engage a focused exchange of information on the pilot research on potato and rice with others scientists in LAC. It is envisaged using this communication channel for posting the cross feeding lessons relevant to other tropical countries. As a first step, the experience gained and general conclusions derived from the close interaction between this pilot research and its partnership with other regional research will be shared. This linkage will be facilitated since some collaborators of Component 4 are also participating in research projects being conducted on rice in Costa Rica (CIAT and ICA, project funded by BMZ, Germany) and on potato in Peru (CIP, project funded by McKnight Foundation, USA). Lessons learned regarding the implementation and operation of the Centers of Excellence, Network for Research, Risk Assessment and Monitoring will also be shared with the community abroad. This set up will bring a dynamic form of learning experience with other countries in the region.

The web site will be linked to other biosafety information sources and to the botanical files once available. It will provide regular updating on the project activities. A discussion forum will be open for public debate.

Under project activities, a project mailing list will be developed in order to enhance the rapid exchange of information between participating parties in order to provide regular updates on significant developments in Biosafety and to facilitate the timely provision of specific information upon request. The data will be presented in a user-friendly way.

The information network and special workshops are aimed to improve the public perception and participation in the process of implementing the project and achieving a better understanding of the National Biosafety Framework (NBF) and the use of LMOs. Media and NGOs working on these issues, will be granted access to the information network. This will ensure the delivery of current and relevant information on Biosafety and related legislation issues.

A four-day Workshop on “Information exchange and Biosafety” will be held to introduce the network as a valuable information source also for public awareness. Hundreds of participants among whom regulators, journalists, scientists, NGO representatives and the general public are expected to attend this event.

Component 4. Centers of Excellence. Network for Research, Risk Assessment and Monitoring

TOTAL COST US\$3,097,946 / BASELINE US\$1,386,637/ GEF US\$387,850/ GOC US\$1,323,459

Centers of excellence (universities, ministries and their related institutions) are an important part of the project as they will be responsible for providing research support, analysis, and training.

A network for research, risk assessment and monitoring will be structured by a Central Node, composed by the executive institutions of the project, and supported by a Network of research institutions to strengthen its research capacity in those specific Biosafety areas where the Central Node does not have the needed expertise. The network as a whole will include an interdisciplinary approach, where expertise on molecular biology, organism biology, population biology, ecology, health and socio-economic sciences are represented. This structure will facilitate the interdisciplinary analysis on a case by case basis, according to needs.

The executive institutions conforming the Central Node could include institutions such as ICA, Institute Alexander von Humboldt, INVIMA, and CIAT. A product of this project is the identification of a list of selected Institutions to lead the Network. As a first approach, a tentative list will be generated using the COLCIENCIAS and other relevant databases from the existing network (agronomy, agroecology, biodiversity and health). This database includes detailed information of Colombian research/ technical groups characterized by area of expertise, number of personnel, qualification of personnel, level of funding, number of publications and patents (International and National), and participation at scientific meetings. A list of institutions with potential to be included in the Network will be generated based on agreed criteria. This list will be posted at the BCH for national and international diffusion. A tentative list of potential Institutional candidates has been identified. This list includes expertise in three key areas of technical capacity identified for risk assessment and monitoring on LMOs.

Central Node Structure and Logistic

The Central Node will include laboratory facilities on molecular biology for risk assessment and monitoring on LMOs for inter-sectoral use (agriculture, livestock, environment, and human health) for the purposes of implementing the Cartagena Protocol. For strategic reasons, these facilities will be located in Bogotá.

Central Laboratory on Molecular Biology

The Central Laboratory will mainly conduct molecular characterization and detection analysis related to LMOs and non-LMOs, support risk assessment and monitoring efforts, and validate and standardize corresponding molecular techniques according to needs. This laboratory will also give support to research activities related to this project, conducted by scientific personnel from the Executive Institutions and/or the Network. During the life of this project, the Central Laboratory will be operated by one coordinator (1), and two (2) technical assistants. The laboratory personnel will be increased as needed. The laboratory facilities will be ascribed to ICA, INVIMA, and Institute von Humboldt to reflect the inter-sectoral operation. This laboratory will count with the necessary equipment and supplies to guarantee operation according to needs.

Support Laboratory

Additionally, the Central Laboratory will count with the scientific/ technical support, expertise, and facilities (Support Laboratory) from the CIAT Biotechnology Research Unit and the Molecular Biology Laboratory of the Institute von Humboldt, and other relevant facilities. The network of

support laboratories will conduct research complementary to the activities of the Central Laboratory on risk assessment and monitoring. The research and methodologies developed in the network will be in close collaboration with the Central Laboratory. To reach this goal and ensure real integration between the two laboratories, an inter-laboratory coordination team will be established; visiting scientist exchange between laboratories will be conducted, and periodic scientific meetings will take place according to needs. The network laboratories should be provided with complementary equipment, personnel, and operational funds necessary to conduct its research activities independently while benefiting from the infrastructure of major equipment and expertise of the host Institutions.

Institutional agreements will be established to structure the network. This network will generate scientific information for the analysis, evaluation, and decision processes applicable to the tropics as well as to increase knowledge on biosafety for LMOs.

Research at the Central Node

In order to implement an active Network from its initial phase and to test the operational aspects for an inter-sectoral cooperation at the Central Node, this project proposes to conduct pilot research on gene flow and its potential impact assessment on native biodiversity in Colombia. This pilot research while generating needed information related to the evaluation and monitoring of potential commercially important LMO crops in Colombia, will allow the establishment of an *in itinere* strategy to prevent, minimize and mitigate potential risks (ex-ante and ex post). Two model crops are suggested for the pilot research, potato and rice, because of their national economic importance, the presence of native biodiversity of land races, wild species or related weeds, and the likelihood to be imported or released as commercial LMOs in Colombia in the near future.

The research projects objectives are: 1) To compile floristic information on *Solanum* and *Oryza* distribution and diversity in Colombia. 2) To identify environmental and biological factors affecting gene flow from two model crops (potato and rice) into other land races and compatible wild species (potato and rice). 3) To identify molecular markers suitable for the evaluation and monitoring of gene flow from potato and rice. This information will aid the design of studies directed to assess potential impact of these crops on non target organisms, and to develop appropriate methodologies for designing refuge areas in tropical ecosystems. The research will draw on the interdisciplinary expertise of various institutions conducting this research (ICA, agro-ecology; Institute Alexander von Humboldt, wild habitat ecology; and CIAT, rice, molecular genetics and agro-ecology). The support of CIP (potato, molecular genetics and agro-ecology) and selected institutions from the satellite node for population genetics will allow a holistic approach.

Releases of transgenic plants in Latin America have involved plants developed outside the region with few exceptions. However the situation is changing and plants are now developed in countries in the region and some research groups are approaching field testing. A case in point is potato. CIP has developed several transgenic potato varieties. The biosafety assessment of these new varieties represents a special challenge to regulatory agencies given the little existing knowledge on risk assessment. In general most risk assessment on the release of transgenic potatoes have been conducted in temperate countries where the possibilities of gene flow to wild *Solanum* populations was virtually non-existent.

As mentioned earlier, Colombia is one of the centers of origin of potato. Substantial research remains to be undertaken to address environmental concerns associated with the release of transgenic potatoes in a center of origin. The expected outcomes of the research will assist Colombia's regulatory authorities to this end. This project will benefit from another project on gene

flow analysis from cultivated potato into wild relatives being conducted in Perú by national research institutions jointly with CIP.

In the case of rice, experimental field trials of transgenic rice with virus resistance have been conducted in Colombia since November 2000. This project will benefit from information generated from another project conducted by CIAT in Colombia and Costa Rica and currently financed by BMZ, Germany, and currently conducted in close collaboration with ICA. The BMZ project is developing methodologies for monitoring gene flow and introgression from rice into compatible wild species/ and the related weedy relative red rice, identified as the main gene flow receptor from the crop. A complete phenotypic and molecular characterization of the diversity of red rice is being conducted with BMZ at the Tolima and Huila Departments. The proposal for GEF project will complement this information with an assessment of the red rice diversity at the Valle del Cauca Department, which jointly with Tolima and Huila, constitute the main rice growing area of Colombia. The new proposal also includes the compilation of botanical file information from National Herbaria on the presence and distribution of wild rice species in Colombia. The data generated will allow the identification of areas with lowest risk for the production of rice LMOs, and the design of appropriate biosafety measurements for this crop in Colombia.

Component 5. *Project Coordinating Unit (PCU)*

TOTAL COST US\$ 181,300 / BASELINE US\$ 0.00 / GEF US\$168,900/ GOC US\$12,400

Responsibility for execution of the project has been delegated by the Ministry of the Environment, which is the GEF focal point in Colombia and to the Alexander von Humboldt Institute (IAvH) where the Project Coordinating Unit (PCU) will be housed. Operational planning, administration, budget approval, annual plans and monitoring of project progress will be under the supervision of an Intersectoral Council (IC) which will be comprised of the Ministry of Agriculture, ICA, Ministry of Health, INVIMA, Ministry of Trade, the Ministry of the Environment, IAvH and Colciencias. The IC will be comprised of people nominated by each of the participating institutions.

The technical and administrative coordination of the project will be the responsibility the PCU located within the IAvH. The PCU will execute the project based on annual plans, and budget which will be approved by the IC. The PCU will oversee the execution of activities and/or subprojects to be executed by the participating institutions as well as monitoring the outcomes. The PCU will develop the annual plans which will be submitted for the approval of the IC. Any adjustments to these plans will require the approval of the IC. The PCU will also prepare and implement the project's monitoring and evaluation system. It will also be responsible for the organization of the meetings of IC and the diffusion of project results and making these known to the public.

The PCU will be responsible for the preparation of all administrative, financial and progress reports for submission to the Bank.

9. RISKS AND SUSTAINABILITY

Risks

A number of project risks have been identified during the course of preparation, and the project design has been modified accordingly. The following table summarises likely risks and describes abatement measures within the scope of the project.

RISK	ABATEMENT MEASURES
Fragmentation of institutional mandates and political cycles may make project implementation difficult.	<p>An Intersectoral Council has been designed to provide appropriate guidance to project implementation and will approve annual work plans and ensure that participating institutions stay focussed on project objectives and outputs.</p> <p>Capacity building exercises in The Intersectoral Council gradually increase and thereby help participating institutions improve overall biosafety policy and program implementation.</p> <p>Project timetable will insure that project is completed during the term of the government which assumes power in August 2002.</p>
Government fails to live up to its counterpart contribution commitments	The identified counterpart contribution is already budgeted within the budgets of participating organizations and ministries. These contributions will be formalized by the PCU in the context of review and approval of the annual work plans.
Industry advances continue to outpace government capacity	During project supervision, these issues will be identified and recommendations made to address them. The Biosafety Clearing House (BCH) will monitor these developments and recommend appropriate reallocation of resources.

Sustainability

This capacity-building project is designed to form the first part of a longer-term national effort to consolidate the Biosafety framework. Each of the proposed activities addresses gaps or barriers that have been identified during the project preparation process. Capacity building activities have been designed to strengthen not only the capabilities of the Colombian focal point to the CP, but also of key ministries, agencies and nodes of excellence. The Intersectoral Council's role as the key technical focal point for the project will help to insure that decision-making will be cross-sectoral and produce synergies among key governmental and –nongovernmental organizations. Financial sustainability is evident in the level of counterpart funding. The results of the project in terms of institutional strengthening and development should lay the groundwork for the allocation of additional resources in the future.

10. STAKEHOLDER PARTICIPATION

Broad-based public consultations on biosafety issues are currently underway in the context of the integration of the National Development Plan. Participants include representatives from all sectors in Colombia. Over the last few years ICA has organized 25 workshops directed to stakeholders, policy makers, scientific community, and civil society. The GEF project will broaden stakeholder participation and public information by including key representatives of each of these sectors in the capacity building component through courses and publications, and through the dissemination of information via the BCH mechanism. Through the BCH mechanism, participation will be supported which will target farmers and other rural organizations and consumer associations. Additionally the BCH will offer the opportunity to create forums on relevant/important biosafety subjects for the purpose of obtaining input from the public at large and feedback on the projects outcomes, particularly at the institutional level. Opportunities will be provided to NGOs, academics and the research community to publish opinions and to disseminate them to the public. Finally, the BCH will disseminate information to different citizen groups interested in Biosafety.

Two regional workshops will be organized with the aim of creating the legislative framework on biosafety and implementation of the biosafety protocol. The workshops will involve not only technical experts and government officials, but also key representatives of civil society (i.e. NGOs, consumer association, the press) to ensure a collective foundation for reaching a broad understanding and endorsement of priority biosafety issues. Such consultation with diverse stakeholders would be fundamental to implementation of this project. This is also reflected in the participation of the media, NGOs, consumer groups and civil society in the training courses of Component 2. Special attention in this course will be given to socio-economic impacts, trans-boundary movement of LMOs, and the Cartagena Protocol.

11. IMPLEMENTATION ARRANGEMENTS

Project Execution

Responsibility for execution of the project has been delegated by the Ministry of the Environment, which is the GEF focal point in Colombia, to the Alexander von Humboldt Institute (IAvH) which will constitute a Project Coordinating Unit (PCU) for this purpose.

Operational planning, administration, budget approval, annual plans and monitoring of project progress will be under the supervision of an Intersectoral Council (IC) which will be comprised of the Ministry of Agriculture, ICA, Ministry of Health, INVIMA, Ministry of Trade, the Ministry of the Environment, IAvH and Colciencias. This Council will be comprised of people nominated by each of the participating institutions.

The Council will approve an operational manual which will be submitted to the Bank for no objection and which will ratify the commitments of each of the participating institutions, establish criteria for the functioning of the Council and define procedures for decision making within the Council as well as the first Annual Operating Plan. Taking into account the actual institutional context in this moment, the Council will define the rules governing its functions, responsibilities and the outputs of each participating institution in the context of the project objectives.

Project Coordinating Unit (PCU)

The technical and administrative coordination of the Project will be the responsibility the PCU located within the IAvH. The PCU will execute the project based on annual plans, and budget which

will be approved by the IC. The PCU will oversee the execution of activities and/or subprojects to be executed by the participating institutions as well as monitoring the outcomes. The PCU will develop the annual plans which will be submitted for the approval of IC.

The PCU will be responsible for the implementation of the overall strategy of the project as operationalized in the annual operating plans which will be approved by the IC. It will also prepare and implement the monitoring and evaluation system and any necessary adjustments to these plans will require the approval of the IC. It will also be responsible for the organization of the meetings of IC and the diffusion of project results and making these known to the public.

The PCU will be responsible for the preparation of all administrative, financial and progress reports for submission to the Bank.

12. INCREMENTAL COSTS ASSESSMENT

This project both complements existing activities described in the section on the current situation (baseline course of action) and adds new activities (alternative course of action) to the baseline that are required to meet the requirements of the Cartagena Protocol and achieve global environmental benefits.

12.1 Baseline Scenario

In the absence of additional GEF funding, a number of activities related to the project's components would be undertaken. The estimated costs of the baseline investment is US\$2,531,237.

Strengthening the legislative framework and operational mechanisms for Biosafety management in Colombia.(\$116,200)

Activities will include an evaluation of the gaps in the current legal and institutional framework for biosafety, support for the Intersectoral Council and the National Biosafety Council and workshops on implementation of regulations which come out the new framework (US\$108,000). INVIMA will organize a workshop related to foods and non-alcoholic drinks derived from LMOs (US\$8,200).

Capacity Building and Establishing of an operational system for risk assessment and monitoring.(\$0.00)

No baseline activities have been undertaken or are under implementation related to this component.

Establishing the biosafety database system and biosafety clearinghouse mechanism.(\$28,400)

ICA will continue to work on activities related to an information database and network containing registers, dossiers, trial data and other related information on Biosafety and EU regulations. The information database will be accessible by all government organizations, NGOs, other interested parties. The database will have an additional regional component containing relevant information on CEE countries or a direct link to their websites and other information sources.(US\$ 28,400)

Centers of Excellence, Network for Research, Risk Assessment and Monitoring. (\$1,386,637)

A number of institutions will contribute to the baseline under this component. The on-going World Bank/GOC PRONATA project will utilize results from research on rice, potatoes and soybeans as

inputs into the capacity and knowledge building at the Centers of Excellence (US\$271,304). The IavH will continue its work on a satellite image data base, ecosystem maps, and a data base on endangered species (US\$ 58,734). CIAT will provide information and analysis for rice gene flow monitoring (US\$130,000) and ICA will coordinate applied research on risk analysis in potatoes and rice (US\$ 60,000). COLCIENCIAS with support from the OAS is undertaking a national study of biosafety and the implementation of the Protocol. (US\$36,600). Finally, the Ministry of Environment and the National Coffee Research Centre (CENECAFE) will undertake a project consisting of both biodiversity analysis and applied biotechnology /genetic research to identify potential economic and scientific benefits associated with small-scale farming in the central coffee zone (US\$830,000).

Project Coordinating Unit.(\$0.00)

No baseline activities have been undertaken or are under implementation related to this component. Funds associated with the baseline for this activity are tied to the approval of the GEF project .

Benefits of the baseline. Benefits achieved by the baseline will permit the GOC to make some progress in meeting its obligations under the CP, especially in the development of the legal and institutional framework, data base development and management, and risk assessment and risk management. However the scope and number of activities financed will be limited nor will the baseline permit the increase in institutional capacity and the development and implementation of the biosafety clearinghouse mechanism. Under the baseline, very few resources will be available for new laboratory equipment and supplies and the establishing dissemination and outreach programs.

12.2 GEF Alternative

The GEF Alternative - the total cost of which is \$4,443,498 will build on the baseline scenario and would support a number of incremental activities needed to meet the objectives of the Cartagena Protocol. Project-related activities include:

Strengthening the legislative framework and operational mechanisms for Biosafety management in Colombia.(Total Costs US\$563,432. Incremental Costs US\$447,432, of which GEF US\$130,928and GOC US\$316,304)

The alternative will provide the means to speed up the whole process in order to put in place the legal and institutional framework for the implementation of the CP. It will also strengthen the interministerial commission in order to facilitate decision making among key institutions related to biosafety regulations and enforcement. Also it will provide the means for better diffusion of the results to stakeholders, both through workshops, analytical material, and guidelines.

Capacity building and establishing an operational system for risk assessment and monitoring.(Total CostsUS\$247,660. Incremental Costs US\$247,660, of which GEF US\$156,000 and GOC US\$91,000)

The alternative will allow for training in: LMOs production and characterization; interaction of LMOs with the environment and health; risk assessment management methodologies; biosafety monitoring and control; legal aspects, and socio-economic issues. It will also provide resources for the preparation of guidelines and the proceedings of the courses.

Establishing the biosafety database system and biosafety clearinghouse mechanism.(Total Costs\$353,085. Incremental Costs US\$324,685, of which GEF US\$131,322 and GOC US\$193363)

The alternative will expand the capacity of the biosafety data base and will bring to its full potential the biosafety clearing house mechanism.

Centers of excellence, network for research, risk assessment and monitoring. (Total Costs \$3,097,946. Incremental Costs US\$1,711,309, of which GEF US\$387,850 and GOC US\$1,323, 459)

The alternative will allow for the purchase of new laboratory equipment and supplies for the central lab which is essential for increasing its capability for risk assessment and to conduct the molecular characterization and detection analysis related to LMOs'. This equipment will supplement existing equipment which is necessary to undertake laboratory testing and analysis.

Project Coordinating Unit (Total Costs \$181,300, Incremental Costs US\$181,300, of which GEF US\$168,900 and GOC US\$12,400)

The alternative will allow the monitoring, of administrative, financial, and operational aspects of the project.

Benefits of the GEF alternative. The GEF alternative will enable Colombia to move more quickly in building the scientific and institutional capacity necessary for meeting its obligations under the CP. Strengthening institutional capacity, purchasing new lab equipment and supplies along with increasing stakeholder participation will be important project outcomes. At the same time, improved coordination of biosafety policy development through the interministerial commission will lay the groundwork for a more solid decision making environment.

12.3 Incremental Cost Assessment

The total cost of the project will be US\$ 4,478,123. The total baseline costs are US\$ 1,531,237. The incremental costs to be provided by GEF will be US\$ 975,000. The GOC will contribute US\$1,937,168 to the project's incremental costs. A total of US\$ 34,700 was used in project preparation under the PDF A. of which US\$ 25,000 was provided by GEF and US\$ 9,700 by the Government of Colombia. A summary of the project's incremental costs are provided in Table 1. The GOC's Incremental costs of US\$1,937,168 will include a cash contribution of US\$1,000,000 which will be provided in Years 2 and 3 of project implementation through the new PRONATA loan. Table II provides a summary of the GOC Incremental Costs (cash vs. in kind). At the time of Project Appraisal the GOC was not able to commit additional cash to their Increment. However, there is a good possibility that in the 2004-2005, additional funds will be made available for GOC programs in biosafety.

Table 1: INCREMENTAL COST MATRIX (US\$)

Component	BASELINE	INCREMENT (GEF)	INCREMENT (GOC)	GEF Alternative
Strengthening the legislative framework and operational mechanisms for Biosafety management in Colombia	116,200	130,928	316,304	563,432
Capacity Building and Establishing an operational system for risk assessment and monitoring	0.00	156,000	91,600	247,660
Establishing the Biosafety Database System and Biosafety Clearing-House Mechanism	28,400	131,322	193,363	353,085
Centers of Excellence, Network for Research, Risk Assessment and Monitoring	1,386,637	387,850	1,323,459	3,097,946
Project Coordinating Unit	0.00	\$168,900	12,400	181,300
Total	1,531,237	975,000	1,937,186	4,443,498

Table II: GOVERNMENT OF COLOMBIA INCREMENT (US\$)

Component	CASH	IN-KIND
Strengthening the legislative framework and operational mechanisms for Biosafety management in Colombia	0.00	316,304
Capacity Building and Establishing an operational system for risk assessment and monitoring	0.00	91,600
Establishing the Biosafety Database System and Biosafety Clearing-House Mechanism	0.00	193,363
Centers of Excellence, Network for Research, Risk Assessment and Monitoring	1,000,000	323,459
Project Coordinating Unit	0.00	12,400
Total	1,000,000	937,186

13. MONITORING AND EVALUATION

Monitoring and evaluation of the project will be based on indicators presented in the project logframe. The relevant data for the analysis of these indicators will be collected during the different project activities, and in the reports prepared by the PCU and participating ministries and agencies. The PCU will prepare monthly status reports and results will be used to fine tune implementation strategies and schedules of the project components.

The PCU will develop a project monitoring system. Quarterly revision of the results of the operative plan of the project will also take place in order for the advances and results of the project to be shared between the beneficiaries of the project and the Intersectoral Council. These revisions will be used to provide quarterly information to the World Bank. The web page, multimedia presentation and videos will also provide needed information on which to evaluate the project's progress and will be updated on a regular basis.

Results of project monitoring and evaluation activities will serve as a basis for the recommendations on changes in project implementation. It is hoped that these results will prove useful as a reference point for the implementation of other similar projects.

In addition, the Bank will undertake periodic supervision such as annual, mid-term and final performance evaluation.

14. PROJECT LINKAGE TO IMPLEMENTING AGENCY PROGRAMS

The project is consistent with the Country Assistance Strategy of the World Bank Group for Colombia, which identifies the protection and the conservation of the environment together with macroeconomic stability and the peace process, as the essential elements to ensure sustainable development. In particular it identifies that special attention should be paid to (1) incorporating environmental considerations and sustainable development incentives into key production sectors and the provision of public service; (2) enhancing capacity of environmental management authorities and seeking opportunities for partnership with other government agencies and the private sector, NGOs and academia; and (3) promoting sector policies and investments to enhance poverty reduction in rural areas. In keeping with this framework, the World Bank supports the implementation of environmental policies in Colombia, education and research in universities, agricultural technology development, and the protection of biodiversity.

Project support related to agriculture and biodiversity conservation is as follows:

The World Bank is supporting the National Agricultural Technology Project (PRONATTA) through a loan of US\$36,000,000. Approximately US\$900,000 of the loan is targeted for work in biotechnology. The loan is supporting activities in the amount of US\$271,304 which form part of the project's Baseline as was discussed in Section 12. Ninety percent of the project's activities have been executed. The products and results of PRONATTA's biotechnology sub-projects have been made available to the relevant governmental agencies concerned with biosafety.

A follow up loan program, PRONATTA II, is under preparation and will be funded in FY 04. The total amount of this loan will be around US\$50,000,000. This Program will establish a competitive fund from which biosafety sub-projects will be funded. At the same time, the new lending program, which envisages competitive support to research and strategic alliances, could support longer-term research and human resource development activities as input into risk assessment of LMOs and

commercial feed and food imports. These linkages will serve to enhance sustainability of the current project's outcomes and results. The GEF project will complement these activities by strengthening the capacity to evaluate technologies, especially LMOs, that might emerge from that program. It is expected that up to US\$1,000,000 will be used from the loan to support activities in biosafety. These costs have been included as GOC Incremental Costs.

Six WB/GEF projects are currently in execution in Colombia:

1. Sustainable Use of Biodiversity in the Western Slope of the Serranía del Baudó (Choco) – Medium Sized GEF – Implementing Agency: World Bank. Executing Agency: Foundation Natura Colombia. The objective of this MSP is the development of a strategy for the sustainable use of biodiversity in the western slope of the Serranía del Baudó and the marine resources of its coastal area (Choco- Pacific Coast). It is a joint effort between governmental institutions and civil society, designed to benefit local communities.

2. Caribbean Archipelago Biosphere Reserve: Regional Marine Protected Area System –Medium Sized GEF – Implementing Agency: World Bank. Executing Agency: CORALINA. The objective of the project is to conserve biodiversity and ensure sustainable use of coastal and marine resources in the Archipelago, while enhancing equitable benefit distribution for the community.

3. Conservation and sustainable use of biodiversity in the Andes region. – Full Size GEF– Implementing Agency: World Bank. Executing Agency: Institute von Humboldt. The project's development objective is to increase conservation, knowledge, and sustainable use of globally important biodiversity in the Colombian Andes. A comprehensive coverage of ecosystems focusing on areas not targeted through the regional projects of the Andean Strategy.

4. Conservation and Sustainable Development of the Mataven Forest (Amazonian) –Medium Sized GEF – Implementing Agency: World Bank. Executing Agency: Etnollano. The objective of the project is to support the indigenous communities of the Matavén Forest to manage and conserve the area's biodiversity in a sustainable way, thereby contributing to an improvement in quality of life and the preservation of their natural and cultural heritage.

5. Initial Assistance to Colombia to meet its obligations under the Stockholm Convention on Persistent Organic Pollutants –Medium Sized GEF – Implementing Agency: World Bank. Executing Agency: Ministry of Environment. The objectives of the project are to: (i) prepare a national Implementation Plan; (ii) build support for Enabling Activities; and (iii) develop indicators for incremental costs through the application and testing of techniques for clean up of POPs sites.

6. Regional Integrated Silvopastoral Approaches to Ecosystem Management Project (Colombia, Costa Rica, Nicaragua)- Full Sized GEF- Implementing Agency: World Bank. Executing Agency: CATIE, Costa Rica, CIPAV, Colombia. The main development objective of this innovative pilot project is to demonstrate and measure the effects of the introduction of payment incentives for environmental services to farmers on their adoption of integrated silvopastoral farming systems³ in degraded pasture lands in Colombia, Costa Rica and Nicaragua and the resulting improvements in eco-systems functioning, global environmental benefits, and local socio-economic gains resulting from the provision of said services.

Two additional WB/GEF projects are under preparation in other regions in Colombia:

1. Conservation of Biodiversity in the Sierra Nevada de Santa Marta – Full Size GEF – Implementing Agency: World Bank. Executing Agency: Fundación Prosierra Nevada de Santa Marta. The objective of this project is to conserve, restore and promote sustainable use of the mosaic of tropical ecosystems in the Sierra Nevada de Santa Marta.

2. Community Based Management for the Naya Conservation (Choco)–Medium Sized GEF – Implementing Agency: World Bank. –Executing Agency: Foundation Proselva, CIPAV and Asociación de Cabildos del Cauca. The objective of this project is the creation of a Biological Corridor Naya-Munchique-El Pinche with the participation of indigenous and African-Colombian communities.

15. LESSONS LEARNED

Colombia participated in all of the negotiations leading up to the signing of the Protocol, and established working contacts with a wide range of countries. The agreements reached in order to move forward with the CP allowed Colombia to understand the needs and priorities of other signatories in Biosafety. More recently, Colombia has participated in diverse meetings on biosafety (IPPC), clearinghouse meetings (Lima, Montreal), OECD-Thailand, and CBD(Cuba) and has used these opportunities to exchange ideas and strategies with countries in the region as well as other mega diversity countries.

Colombia has previously carried out self-assessments of national capacities and gaps in the framework of the enabling activities in climate change and biodiversity. The current project takes into account these previous experiences and concretely builds on the national biodiversity information system housed in the Von Humboldt Institute. At the same time, the intersectoral working group has raised awareness of the gaps in the national legal framework for Biosafety and has promoted broader dialogue with all the stakeholders. During the project preparation process, the project team has promoted wider dialogue and consensus between the different agencies and organizations represented by the intersectoral working group, and has helped to achieve consensus on national priorities in relation to LMOs. This improved co-ordination and dialogue is a key aspect of the proposed capacity building activity with the GEF.

Annexes:

A. Project Logical Framework

B. Chronogram of activities

C. Project Endorsement Letter from GEF Focal Point

D. GEF (STAP) Technical Review and Bank Response to STAP Review

Annex A:

PROJECT LOGICAL FRAMEWORK

Each of these five main components has intermediate outputs expected which will be reached by diverse activities carried out by the main participants of the project.

Objective	Activities	Success Indicator	Unit of Measurement	Number of units	Way of Verifying
Project set up	Establishment of a coordinating unit	Coordinating Unit created	Coordinating unit	1	Work Plan for coordination
1.Development of the legislative framework	Development of normative tools	Adjusted law project	Law Project	1	Presentation to Congress
	Development of coordination mechanisms and designation of the national authorities and the national focal point	Focal point and competent authorities are named	Regulations	Undetermined	Administrative Acts
	Strengthening of working groups on Biosafety at the different ministries involved	Ministry work groups are created	Ministry work groups	4	Action plan for the ministry work groups
	Development of guidelines, procedures and handbooks for notification, advance informed agreement procedures on transit , production, commercialization and use of LMO's in the country	Guides routes and validated procedures	No. of guide documents	Undefined	Guides, routes and public procedures
2.Development of Institutional capacity	Design and creation of capacity on biosafety among key stakeholders	Capacity on Biosafety , working in each one of the different institutions.	Number of institutional participants working	3	Action Plan on training
	Design of a training program oriented to capacity building for techniques and monitoring	Designed program based on the conceptual framework	Number of designed courses and exchanges	1	Defined program
	Biosafety course on LMO's 1 Level	2 Courses conducted	No. of trainees	60	Evaluation of courses
	Biosafety course on LMO's 2 Level	1 Course conducted	No. of trainees	15	Evaluation of courses
	LMO's molecular and phenotype characterization course	1 Course conducted	No. of trainees	10	Evaluation of courses

Objective	Activities	Success Indicator	Unit of Measurement	Number of units	Way of Verifying
	LMO -Environment interaction course	1 Course conducted	No. of trainees	40	Evaluation of courses
	LMO -Health interaction course	1 Course conducted	No. of trainees	20	Evaluation of courses
	Microorganisms Biosafety LMO's	1 Course made	No. of trainees	30	Evaluation of courses
	Social-economic and legal aspects of LMO's	1 Course conducted	No. of trainees	60	Evaluation of courses
	Short term Exchanges	Exchanges made	No. of exchanges	10	Evaluation of program
	Medium Term	Exchanges made	No. of exchanges	6	Evaluation of program
	Memories of courses as a base for biosafety manuals	Programmed Proceedings	No. of memories	7	Edited Proceedings
	Biosafety Guides	Biosafety Guides	No. of guides	3	Edited Guides
3. Establishment of Biosafety Clearing House	Physical location of the BCH	Preparation of headquarters	Headquarters adapted and established	1	Direct verification in situ
	Hiring of staff	Hired personnel	Formation of the team	2	Contracts
	Equipment	Technical infrastructure purchased and functioning	List of equipment	12	Direct verification, and proof of purchase
	Software acquisition	Software running	Working permits	5	Direct verification and permits
	Provisions maintenance and materials Purchase	Material bought	Materials		Proofs of purchase (receipts)
	Local network connection	Connection working	Connection	1	Contract
	Identification and detailed design of the information components that the BCH will have	Structured components	Components	10	Document
	Web Page design	Web page running on the internet	Web Page	1	Internet
	Detailed design of information capturing mechanisms	Standardized mechanisms of capture and exchange	Exchange and capture protocol	1	Written procedures

Objective	Activities	Success Indicator	Unit of Measurement	Number of units	Way of Verifying
	Design and management of data base	Data base working with proper information	Data base		data bases
	Manual and operational design.	Clear manual published	Manual	1	Document
	Information gathering	Capture mechanisms and information exchange	Systemized information		database
	Training for BCH staff	Personnel with the capacity for information sharing required for the BCH	No. of courses and trainings	2	Proceedings and reports
	Spreading information tools	Tool kit designed	KIT	1	Documents
	Inauguration of the BCH	Inauguration event	Event	1	proceedings of the event
4. Development of nodes of excellence	Design and creation of capacity nodes in Biosafety: Central nuclei tri-institutional (ICA-INVIMA-IAvH), support satellite nuclei of other support institutions)	Nodes of excellence on biosafety functioning	Nodes of excellence on Biosafety	2	Schemes and programs of nodes of excellence
	Reconditioning of central tri-institutional lab	reconditioned institutions	reconditioned M ²	1	Progress reports
	Equipment of central tri-institutional lab	Equipped lab	List of acquired equipment	list	Direct verification of purchase invoice
	Personnel hiring for the operation of the lab	Personnel hired	Work team formed	2	Contracts
	Techniques validation to be executed in the tripartite lab.	Validated techniques	No. of techniques.	To be defined	Technical support of the validations.
	Development of the activities of sample monitoring	Performed analyses	No. of samples.	According to demand.	Report of performed activities.
	Equipment of support lab CIAT IavH	Equipped lab	List of equipment	list	Direct verification of purchase invoice
	Hiring of personnel for the support lab CIAT IavH	Conformed team	No. of contracts	2	Contracts

Objective	Activities	Success Indicator	Unit of Measurement	Number of units	Way of Verifying
	Research and development of new techniques in the lab	Identified and developed techniques.	No. of techniques	To be defined	Techniques protocols.
	Formulation of research projects	Consolidated projects	Number of projects	2	Texts of the project.
	Execution of projects	Accomplished objectives	% of accomplishment	2	Reports of advanced.
	Experiences synthesized	Publications	No of publications	To be defined	Cosignatory
	Use of the results of risk analyses research	Level of the results for risk analyses	Number of attended requests and referrals of information use.	To be defined	Reference of use

Annex B:

TIMETABLE OF ACTIVITIES

General Activities Chronogram												
Activities	TIME (annual trimesters of the project)											
	YEAR 1				YEAR 2				YEAR 3			
	1	2	3	4	5	6	7	8	9	10	11	12
ESTABLISHMENT OF COORDINATING UNIT												
Establishment, location , appropriateness and securing of the physical space of the coordinating unit												
Operationalize unit												
LEGISLATIVE FRAMEWORK												
Inter-institutional and regional adjustments, discussion of the first draft.												
Legislative Biosafety framework Project												
Presentation of the first draft of Biosafety law to the government and subsequently through it to congress												
Designation of the competent authorities and the focal point.												
Development of operational manual and procedures for notification and Advanced Informed Agreement of LMO's in transit, and/or mobilization, production, commercialization and use of LMO's in the country.												
Execution and adjustments to the defined procedures.												
Create and execute coordination mechanisms.												
Capacity strengthening at ministerial level.												
INSTITUTIONAL CAPACITY												
Design and creation of Biosafety capacity.												
Adjustment to the capacity building program for the development of knowledge nodes.												
Introduction to LMO's Biosafety Level 1.												
Introduction to LMO's Biosafety Level 2.												
Molecular and phenotypical characterization of LMO's												
Interaction LMO's-environment.												
Interaction LMO's-Health												
Biosafety on microorganisms –LMO's.												
Social economic and legal aspects of LMO's												
Short term internships.												
Medium term internships												
Proceedings of the courses												
Biosafety guides												
BCH information exchange mechanism												
Physical location of BCH.												
Hiring of human resources.												

General Activities Chronogram

Activities	TIME (annual trimesters of the project)											
	YEAR 1				YEAR 2				YEAR 3			
	1	2	3	4	5	6	7	8	9	10	11	12
Purchase of servers.	■											
Purchase of computers	■											
Purchase of printers	■											
Purchase of Xerox machine	■											
Purchase of telephone and fax	■											
Purchase of working places and meeting.	■											
Purchase of software	■											
Purchase of supplies, maintenance and materials	■											
Connection to local network	■											
Identification and detailed design of the information components for the BCH.		■										
Web page design.			■									
Detailed design of the mechanisms to capture and exchange information.			■									
Database design and management.				■								
Design of the operational manual of BCH					■							
Information gathering						■	■	■	■	■	■	■
Evolution of the gathered information.						■	■	■	■	■	■	■
Design of dissemination tools.			■	■			■	■			■	■
Launching of BCH				■								
Presentation of reports to coordination unit.			■			■			■			■
CENTRAL LAB NODES												
Physical repairs to lab	■	■	■	■								
Purchase of lab equipment.	■	■	■	■								
Hiring of lab assistants.					■	■	■	■	■	■	■	■
Validation of molecular analyses techniques.					■	■	■	■	■	■	■	■
Identification of specific primers					■	■	■	■	■	■	■	■
Molecular analyses of LMO's					■	■	■	■	■	■	■	■
Project. Gene flow risk assessment of cotton Potato and rice for the management of LMOs in Colombia												
Survey of genetically compatible populations	■	■	■	■								
Assembling distribution of wild/weedy relatives / land races and crop contact zone in computer package	■	■	■	■	■	■	■	■				
Development of molecular tools and interdisciplinary strategy for the evaluation and monitoring of degree of gene flow from these crops at crop contact zone and under experimental conditions	■	■	■	■	■	■	■	■	■	■	■	■
Information exchange with other research groups on rice and potato in LAC, and general conclusions derived for application to Neotropical countries					■	■	■	■	■	■	■	■
Dissemination of results through the national regulatory bodies, and to other institutions through the BCH mechanism									■	■	■	■

Annex C:

STAP Review

Capacity Building for Implementation of the Cartagena Protocol in Colombia

Reviewer: Ariel Alvarez – Morales

Component 1: Strengthening the legislative framework and operational mechanisms for Biosafety management in Colombia

Most of the legislative propositions I have had a chance to review from Latin American countries are based, or tend to be based, on certain characteristics of the technology involved in obtaining a LMO. This focus on technology may possibly have consequences in the medium or even short term. As science and technology in the biological area is evolving so fast, it may be impossible to predict new ways in which organisms may be genetically altered, in vivo and in vitro, therefore creating possible legal loop holes in legislation that was intended to oversee a strictly defined regulated article, organism, or event.

It may be prudent to include in the project a period of time to discuss whether a law is convenient versus more flexible instruments, such as norms, rules or guidelines, at least during a time that would also allow for more experience to be gained before a commitment is made to obtain a long lasting law.

A comparison of the legal framework from different countries could also be highly beneficial.

Response: *Although the last objective is certain to count with a Law Frame on Biosafety for protection of health human, animal and and agricultural, environmental and the well-being of socioeconomic population, applied in a harmonic and coherent way (with a set of normative instruments that develops it), the project recognizes that this is a medium term process that considers national procedure (design, agreement, radification by the National Congress, debate and expedition). For this reason the project proposes in a short term the creation of the National Commission of Biosafety- NCB as an advisory high level interinstitutional mechanism. The experience gained by the NBC during the course of the approval of the Law will allow the development of inputs into the design and arrangements of the same one. In other words in a short term, it would not be the implementation of binding normative instruments.*

Component 2. Capacity building and establishment of an operational system for risk assessment and monitoring

It is a very important area where I have concerns about how it is planned and implemented. First, the number of trainees seems excessive and it is not clear why so many need training.

a. Two training courses for 60 trainers from the Ministries of Agriculture and Rural Development, Health, Environment, International Trade, policy makers, NGOs, media, consumer and producer groups. This course will specifically focus on contained, deliberate release and commercial use of LMOs. This course would emphasise biosafety issues from an interdisciplinary perspective, including general technical background for risk assessment and management of LMOs, LMOs under agriculture settings, and interactions of LMOs with non-target organisms. Equal

attention will be given to molecular biology, organism biology, population biology and ecology under an environmental context, as well as to health factors .

Some comments:

- At what level will this course be given to be amenable to such a highly diverse group of trainees?
- How will the trainees be selected?
- What profile or background experience would you require from these trainees?
- Will all trainees actually be involved in biosafety issues, or somehow involved in achieving the goals of the project?

b. A workshop for 60 representatives of government, media, NGOs, consumer groups and scientific community on socio-economic and legal aspects related to LMOs. Special attention will be given to socio-economic impacts, trans-boundary movement of LMOs, and the Cartagena Protocol.

Some comments:

- Will participants from the course described in a) be involved here?
- How is the knowledge obtained by this group of participants related to the first course?
- How will participants in this workshop interact with those taking training course mentioned above in **a**?
- Will all trainees actually be involved in biosafety issues, or somehow involved in achieving the goals of the project?

c. Five courses of three-to-twelve-day each for a total of 115 representatives of government dealing with risk assessment, risk management, and research, and selected scientists from the centers of excellence network (Component 4). These courses will be of higher knowledge level and technical specialisation on interdisciplinary biosafety issues, including general technical background for LMO risk assessment and management, LMOs under agriculture settings, and LMOs interactions with the environment and health. The two model crops (proposed for research in Component 4) will be used as case studies for discussion of ex-ante biosafety strategies.

Some comments:

- Will trainees from the courses described in **a** and/or **b** be involved in this course?
- Since scientists are being selected, how is it expected that they contribute to achieve the goals of this project?
- How will the experience gained through these courses be channeled to achieving the goals of the project?
- How are all these people be coordinated?

Response: *In agreement with the project text, the courses have been planned considering the domain and experience of the participants. The first group of workshops is directed at providing a general background on LMOs and Biosafety in the context of the Cartagena Protocol . In particular, the first training program(a) is directed at regulatory agents and policy makers, selected according to their background and addresses aspects such as evaluation and handling with risks, tests to detect the presence of LMOs, administrative mechanisms for the fulfilment of the legislation, processes and mechanisms of coordination of the involved organizations and the control of the*

transbordering movement. The second group of workshops (b) will provide in depth understanding of the prevention of adverse effects and protection of the biodiversity. The workshops and training described in (c) and (d) will depend on different methods of evaluation of risks and stages directed to the institutions from support to the nodes of excellence and equipment of the institutions that evaluate, pursuit, control and monitor, and research.

In general all the participants will have a continuity within them in their training process according to their competition.

Component 3. Establishing the biosafety database system and Biosafety Clearing-House Mechanism in Colombia

This part of the proposal is well planned and structured. It takes into account the need to share information with other countries in the region. This should serve to avoid duplication and to share experience.

Component 4. Centers of Excellence. Network for Research, Risk Assessment and Monitoring

It is mentioned that research groups or institutions could be selected by using the COLCIENCIAS database which takes into account information regarding items such as number of publications, patents, level of funding, etc. In my opinion it is also important not to dismiss the possibility of people, groups or institutions conducting highly relevant practical work in agronomy, or field ecology, and who may not have patents or international publications. These should actually be given more attention.

I wholly agree with the proposal to focus research on potato and rice as pilot systems, as well with the idea of performing research that certainly will be needed in the near future and not wait until it is required, as usually happens in most Latin American countries. This should set a good example and a good precedent.

Furthermore, a strong research program aimed to investigate the effects that cultivated varieties (not transgenic) have already had on the ecology of wild relatives could be very important to understand the possible effect of transgene flow on these same wild relatives. This would also serve to better understand if genes from cultivated varieties have introgressed and have been maintained in wild or feral populations of sexually compatible species.

Response: *As mentioned in the project, the Colciencias database will serve as the first source, it does not constitute the only source. The text has been modified as follows:*
(Pag. 14) *As a first approach, a tentative list will be generated using the COLCIENCIAS⁴ and other relevant databases from existing networks in related areas including agronomy, agroecology, biodiversity and health. A list of institutions with potential to be included in the Network will be generated based on agreed criteria. This list will be posted at BCH for National and International diffusion.*

Component 5. Project Coordinating Unit (PCU)

In my opinion, this is a very crucial part of the project that has been well thought and planned. My only comment is that all members of the team should be highly motivated people and not

⁴ This database includes detailed information of Colombian research/ technical groups characterized by area of expertise, number of personnel, qualification of personnel (Ph.D., Master, and Bachelor degrees), level of funding, number of publications and patents (International and National), and participation at scientific meetings.

necessarily high-ranking officials so that this group does not experience problems with meeting attendance.

ANNEX D

Matrix showing the relation between the project activities, the Cartagena Protocol and the National Biosafety Framework

ACTIVITY	LINKAGE TO THE NATIONAL BIOSAFETY FRAMEWORK	LINKAGE TO CARTAGENA PROTOCOL (ARTICLES)
<ul style="list-style-type: none"> ▪ Evaluate the existing regulatory instruments and develop others which will ensure an adequate level of protection in the field of the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology. ▪ Creation of a high level interinstitutional mechanism - National Biosafety Council (NBC)). ▪ Two regional workshops will be organized with the aim of creating the legislative framework on Biosafety. 	<ul style="list-style-type: none"> ▪ Elaborate a legal proposal for the creation of the Intersectorial Biosafety Commission. ▪ Elaborate and develop a plan for intersectorial coordination related to information on LMOs and their derivatives. ▪ Propose strategies for the incorporation of the legal framework and related policies into the decision making process for sector projects and programs which are focused on LMOs and biosafety. 	<p>2(2), 8(2), 11(2), 9(3), 10(1), 16(3) 16 (4), 17 (1), 18(2a), 18 (2b), 18(2c), 21 (1,6) 21(2), 21(3,5), 21(4), 25(1), 25(2)</p>
<ul style="list-style-type: none"> ▪ Two training courses for trainers targeted at policy makers, NGOs, media, consumer and producer groups focus on contained, deliberate release and commercial use of LMOs. ▪ A workshop for representatives of government, media, NGOs, consumer groups and the scientific community on socio-economic and legal aspects related to LMOs. ▪ 5 courses for representatives of government and selected scientists from the centers of excellence network dealing with risk assessment, risk management, and research. ▪ 10 short term and 6 long term visiting scientists exchanges to allow more specialised training of selected technical personnel. 	<p>Promote the development of institutional capacity on biosafety and establish mechanisms for risk management including:</p> <ul style="list-style-type: none"> ▪ Evaluation and analysis of information related to LMOs ▪ Monitoring, and control of use of LMOs ▪ Increasing public awareness and participation 	<p>15(1,2), 16(1), 16(3), 17(1), 20(3) (c, e), 25 (3), 33</p>

<ul style="list-style-type: none"> ▪ Establish a network of laboratories which will promote strategic alliances among national research organizations 		
<ul style="list-style-type: none"> ▪ Establishment of infrastructure and logistics ▪ Creation of a team of experts ▪ A four-day Workshop on “Information exchange and Biosafety ▪ A quarterly newsletter ▪ Design and maintain an information network 	<ul style="list-style-type: none"> ▪ Propose and develop mechanisms for the effective interchange of scientific, technical, legal and administrative information or other information deemed relevant at the national, regional or international level. <ul style="list-style-type: none"> ▪ A national system of information on biosafety that includes mechanisms related to the provisions of the Cartagena Protocol (ie Biosafety Clearing House) ▪ Training in the efficient management of information 	<p>20, 23(1a) 23(1b) 23(2) 23(3)</p>
<ul style="list-style-type: none"> ▪ Establish centers of excellence ▪ Establish a network for research, risk assessment and monitoring by a Central Node ▪ Improve laboratory facilities and support laboratories including molecular biology for risk assessment and monitoring on LMOs ▪ Establish two pilot research (model crops suggested) 	<ul style="list-style-type: none"> ▪ Promote the development of institutional capacities in the area of biosafety among key institutions with responsibilities for overseeing matters related to LMOs. In this context establish mechanisms for: <ul style="list-style-type: none"> ▪ Creation of research groups on Biosafety to provide technical support for decision making at the sectorial level ▪ Risk management ▪ Evaluation and analysis of information on LMOs ▪ Creation of a national data base ▪ Control and monitoring of LMOs ▪ Building the required infrastructure for control and monitoring 	<p>15(1,2), 16(1), 16(3), 17(1), 20(3) (c, e), 25 (3), 33</p>

Colombia: Capacity Building for the Implementation of the Cartagena Protocol

German Comments on a GEF Proposal

Comment. The proposal recognizes that Biosafety is a cross-cutting issue and does not belong to the responsibility of one single ministry. The Interministerial Commission, referred to under 12.2 GEF Alternative, does not appear in the project components. Thus, within the proposal, no concrete measure is planned that would enhance inter-ministerial cooperation (with the exception of the Intersectoral Council, but this has only supervising functions and meets not more than twice a year).

Response. *The Interministerial Commission is not included as a specific component because the development of its capacity will be a product of project activities particularly under Component 1. The Intersectoral Council has more than supervisory functions. Its role as detailed in Section 11, Institutional Arrangements, is to develop operational plans, approve budgets, and monitor the project's progress. The IC has broad representation including all relevant ministries (Health, Environment, Trade, etc.). Finally, the National Biosafety Council will also be created under the project and will advise the government on the adoption of policies, regulations and the unified decisions on biosafety. It will be comprised of three Technical Committees with expertise in environment, health and agriculture. Each of these bodies is multi-sectoral in representation and through the project's activities opportunities for improved coordination will be enhanced.*

Comment. The first measure mentioned under Component 1 (legislative framework) are regional workshops. This does not reflect the fact that a legislative framework is a national duty! There is nothing to say against inviting international/regional experts for framework development, but the decisions have to be taken within Colombia. Regional workshops are more likely to serve training or best practice dissemination.

Response. *The word "regional" in this context applies to the regions of Colombia not the region of Latin America. The regional approach is adopted so as to enhance the participation of various civic group in developing the legislative framework.*

Comment. Under component 4 (research) special attention has to be given to possible overlaps with the BMZ funded research project, mentioned in this same section (no double funding!).

Response. *Thanks for bringing this to our attention. The Task Manager will communicate this information to the implementing agency and will follow up with formal contacts.*

Comment. There is another point of contact with German activities in Colombia: The Ministry of Environment has submitted a proposal for education and communication in biosafety issues to the GTZ sectoral project Implementing *the Biodiversity Convention* within the German Biosafety Capacity Building Initiative. This proposal is not mentioned in the GEF proposal. Apparently, there are no overlaps between the two respective projects (the one to GTZ deals with school curricula, multipliers and public education,

not with the training of experts), but there has to be kept an eye on, when it comes to the implementation of the two projects.

Response. *You have correctly pointed out that there are no overlaps between the GTZ and the GEF project. However the Task Manager will again establish contacts with this initiative.*

Margaret Isaac

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