MEDIUM-SIZED PROJECT PROPOSAL
REQUEST FOR GEF FUNDING

AGENCY'S PROJECT ID:
GEF SEC PROJECT ID: 2997
COUNTRY: Vietnam
PROJECT TITLE: Implementation of the National Biosafety Framework of Vietnam
GEF AGENCY: UNEP
OTHER EXECUTING AGENCY(IES):
DURATION: 48 months
GEF FOCAL AREA: BD
GEF OPERATIONAL PROGRAM: EA
GEF STRATEGIC PRIORITY: BD3
ESTIMATED STARTING DATE: January 2006
IMPLEMENTING AGENCY FEE:

FINANCING PLAN (US$)	
GEF PROJECT/COMPONENT	
Project	997,800
PDF A*	
Sub-Total GEF	997,800
CO-FINANCING**	
GEF Agency	
Government	637,000
Bilateral	
NGOs	
Others	
Sub-Total Co-financing:	637,000
Total Project Financing:	1,634,800
FINANCING FOR ASSOCIATED ACTIVITY IF ANY:	

* Indicate approval date of PDFA
** Details provided in the Financing Section

CONTRIBUTION TO KEY INDICATORS OF THE BUSINESS PLAN: The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area it is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety

RECORD OF ENDORSEMENT ON BEHALF OF THE GOVERNMENT:

(Enter Name, Position, Ministry)	Date*: (Month, day, year)*
GEF Focal Point of Vietnam, Dr. Pham Khoi Nguyen	Letter of endorsement signed by GEF Operational Focal Point on 18 October 2005.

This proposal has been prepared in accordance with GEF policies and procedures and meets the standards of the GEF Project Review Criteria for a Medium-sized Project.

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LIST OF ACRONYMS

CBD=	Convention on Biological Diversity
CP=	Cartagena Protocol
MONRE	Ministry of Natural resources and Environment
MARD	Ministry of Agriculture and Rural Development
MOI	Ministry of Industry
MOFI	Ministry of Fisheries
MOH	Ministry of Health
MOSTE	Ministry of Science, Technology and Environment
MOF	Ministry of Finance
NCA	National Competent Authority
NEA=	National Executing Agency
NPD=	**National Project Director**
NPC =	National Project Coordinator
NCC =	National Coordinating Committee
NAPB=	**National Action Plan for implementation of the Cartagena Protocol until 2010**

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A. PROJECT SUMMARY

Viet Nam ratified the Convention on Biological Diversity on 17 November 2004 and the Cartagena Protocol on 19 January 2004.

The Government of Viet Nam attaches great importance to formulating policies that facilitate the development of science and technology, especially biotechnology (Resolution No. 18 NQ/CP dated 11 March 1994 on the development of biotechnology in Vietnam by 2010), as a key national program for socio-economic development.

Hand-in-hand with promoting the development of biotechnology, Vietnam also pays due attention to, biosafety management. In Viet Nam's Agenda 21, safe use of biotechnology is mentioned as an approach to achieve sustainable development goals through an emphasis on promoting research and development of biotechnology whilst protecting biodiversity, the environment and human health.

Towards this purpose, Vietnam participated in the Global Project on "Development of National Biosafety frameworks". In order to design its **National Biosafety Framework (NBF).** Viet Nam is now requesting further assistance from GEF in order to operationalise its NBF. Following the completion of the draft NBF, the Vietnam Prime Minister has issued Decision No 212/2005/QD-TTg dated August 26,2005 on "Regulation of biosafety management to genetically modified organisms, goods and products originated from GMO".

Project Goal

The **overall goal** is to assist Viet Nam to have a workable and transparent national biosafety framework by 2010, to fulfil its obligations as a Party to the Cartagena Protocol on biosafety, and to comply with the country's Agenda 21, the government strategy on development of biotechnology (Resolution 18/CP), and the National Action Plan for biosafety (NAPB).

Specific Objectives:

A. To assist Viet Nam to integrate and incorporate safe use of biotechnology into national sectoral action plans and strategies in conformity with the national Agenda 21.
B. To strengthen the legal and regulatory framework on biosafety so that it is consistent with the Cartagena Protocol, workable and responsive to national needs and priorities.
C. To set in place a workable system for handling requests, carrying out risk assessment, and decision making for GMOs.
D. To set in place a workable and effective national system for monitoring and enforcement
E. To establish a workable and effective national system for public awareness, education and participation in decision-making for GMOs.

Project Outputs

A1. Government recognises the importance of biosafety for sustainable development by approving the National Action Plan on Biosafety to 2010.
A2. Biosafety action plan integrated into national sectoral plans and strategies for Biodiversity, environmental protection, Biotechnology, Agriculture, Fisheries, Trade, and Health.

B1. A regulatory regime in place for management of GMOs.

B2. Biosafety regulations formulated for GMO management in different sectors.
B3. Biosafety regulations formulated and promulgated for trade in GMOs and their products.

C1. A fully functional administrative system for handling requests for GMOs in place.
C2. A fully functional system for risk assessment in place.
C3. A fully functional system for decision making in place.
C4. Strengthened capacity for the safe development and use of biotechnology in Viet Nam.

D1. Well-defined roles and responsibilities of NCAs for monitoring and enforcement established.
D2. Strengthen capacity for enforcement of decisions.
D3. Emergency response procedures (ERP) established and in place.

E1. Strengthened systems for access to, and sharing of information.
E2. A strengthened system for public awareness on the safe use of GMOs..
E3. Strengthened system public participation in decision making on GMOs.

Estimated budget (in US$:

GEF: Project Cost:	US $997,800
Co-financing: (Vietnam government	US $637.000
In cash:	US $65,000
In kind	US $572,000
Total:	**US $1,634,800**

Information on Project proposer.

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B - COUNTRY OWNERSHIP

B1. Country eligibility

Viet Nam ratified the Convention on Biological Diversity on 17 November 2004 and the Cartagena Protocol on 19 January 2004.

B2. Country Driveness

State Project linkage to national priorities, action plans and programmes:

In the late 1980's Vietnam initiated a reform of its economic management system and its integration into the regional and global society, known as *doi moi.* This reform has been successful in promoting economic growth, bringing large numbers of people out of poverty, assuring that the basic needs of the growing population are met, and modernising the economy and society. Reform and the development process in Vietnam is driven by national, provincial, regional and sectoral socio-economic development strategies and plans.

Over the past decade the government has taken key steps to manage the environment. The Law on Environmental Protection was issued in 1993, followed by an array of decrees, directives and circulars. Laws regulating land management, water management and forestry management have also been issued. Many action plans and strategies have developed and implemented , including the National Conservation Strategy (1986), the National Plan for Environment and Sustainable Development (1992), annual State of the Environment Reports (since 1994), the National Environmental Action Plan and the Biodiversity Action Plan (1995), and the National Strategy for Environmental Protection (NSEP, 2003).
Vietnam's strong support for international agreements on environment protection is shown through its ratification and implementation of environmental conventions pertaining to biodiversity, climate change. On January 19, 2004 Vie tnam became a Party to the Cartagena protocol on Biosafety.

The State and Government attaches great importance to formulating policies that facilitate the development of science and technology, especially biotechnology. Resolution No. 18 NQ/CP dated 11 March 1994 on the development of biotechnology in Vietnam by 2010 clearly states: "biotechnology is defined and recognized as one of key national programs in socio-economic development".

Coupled with promoting the development of biotechnology, Vietnam is also well aware of, and pays due attention to, biosafety management. Biosafety become a new priority of Government. In Viet Nam's Agenda 21, safe use of biotechnology is mentioned as an approach to achieve sustainable development goals through an emphasis on promoting research and application of biotechnologies to develop breeds of domestic animals and plants that have high productivity, good quality and strong resistance against pests and disease but without any adverse impacts on bio-diversity, the environment and human health.

The Government's commitment to biosafety was demonstrated by Decision No 212/2005/QD-TTg dated August 26,2005. This decision, drafted as part of the NBF, covers biosafety management for scientific research, technology development, production, trading and usage, import, exports, transportation of GMOs and related products.

C – PROGRAM AND POLICY CONFORMITY

C1. PROGRAMME DESIGNATION AND CONFORMITY

The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area. It is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety, i.e. "Developing systemic and institutional capacity building for biosafety: Provision of support to countries for the development and implementation of National Biosafety Frameworks including the Biosafety Clearing House and enabling activities including the development and training in risk assessment and management of modified living organisms with the participation of relevant government sectors such as agriculture, fisheries, forestry, industry, environment, education, manufacturing, trade and health as well as community and private sector stakeholders."

It is therefore most relevant to the implementation of GEF Operational Programs (OPs) 1-4 and 13.

C2. PROJECT DESIGN

C2.A BACKGROUND AND CONTEXT

Vietnam participated in the Global Project on "Development of National Biosafety frameworks". In order to design its **National Biosafety Framework**, Vietnam carried out the following activities:

- ? Inventory of current use of modern biotechnology as defined in the Cartagena Protocol on Biosafety;
- ? Existing legislation or legal instruments related to biotechnology / biosafety, etc.;
- ? Inventory of active or planned National Projects for capacity building related to the safe use of biotechnology;
- ? Inventory of existing sub-regional biosafety frameworks and mechanisms for harmonization of risk assessment/management;
- ? Development of regulation on management of GMOs and their products;
- ? Publication of following awareness materials: Explanatory guide to the Cartagena Protocol (translated document), Biosafety and the Environment (translated document), Pockets of knowledge" on crop biotechnology (translated document), Biosafety: Risk assessment and risk management, LMOs: challenge or opportunity;
- ? Organising meetings and workshops to disseminate and raise public awareness on biosafety: Workshop on Cartagena protocol on biosafety; Training workshop on Legal and Administrative Aspects on Biosafety; Stakeholder workshop to identify key components of NBF; Training Workshop on Risk assessment and Risk Management; Workshop on legal framework for biosafety management; Stakeholder workshop on final draft of National Action Plan to implement the Cartagena Protocol on Biosafety.

The National Action Plan for implementation of the Cartagena Protocol on Biosafety was prepared under the NBF project. This Action Plan puts forward five programmes to be implemented till 2010; these include: Strengthening legal and regulatory framework on biosafety; Promoting state management capacity in biosafety; Capacity building in biosafety research; Raising public awareness, information sharing and public participation in biosafety management; Enhancing international cooperation in biosafety.

The draft National Biosafety Framework, prepared under the NBF Development project, is available at: http://www.unep.ch/biosafety/development/Countryreports/VNNBFrep.pdf

C2.B CURRENT SITUATION (IN THE COUNTRY WITH RESPECT TO THE NBF)

Vietnam has made legal commitments towards the safe use of biotechnological productions both at the international and national levels. In the international context, Vietnam has ratified the Convention on Biological Diversity, adopted Agenda 21, and is a Party to the Cartagena Protocol since April 2004.

A. Biosafety policy

Under the guidance of the Party and State at central and local levels, biotechnology in Vietnam has achieved encouraging results over the last few years. Since the mid-1990s, the Party and State of Vietnam have attached great importance to development of biotechnology, considering it as one of the four key scientific and technological areas of the country. The Political Report of the VIII Party Congress clearly points out "Perception and master of advanced technologies such as information technology, biological technology, new material technology, new technology in machinery engineering and so on are needed to quickly enter into modernization in key areas"[1]. Specifically: "Develop biotechnology to create and breed new varieties ; processing of agricultural, forest and aquaculture products; production of different vaccines and antiserum, products for quick and accurate diagnosis; develop technologies for environment pollution treatment... Establish high-tech zones in Ha Noi and Ho Chi Minh City (including biotechnology) as the hub of domestic and foreign agencies and enterprises in the field of high technology and high-tech based industries"[2].

The 6th meeting of the Central Committee of the IX Party Congress on science and technology reaffirmed that: "The second line of priority is to develop biotechnology, focusing on research and application for developing agriculture, forestry and fishery, food processing, protection of human health and environment. It is of special importance to build and develop gene technology, biochemical and enzyme technology, cell technology, micro-organism technology, and ferment technology (as key technologies of biotechnology)"[3].
On 11 March 1994, the Government promulgated the Resolution 18/CP on development of biotechnology in Vietnam to 2010, clearly stating the standpoints of the Vietnamese Government about biotechnology as follows:

a) Developing biotechnology in such a way to optimally exploit the biological resources of the country and at the same time duly considering the protection and development of the biological resources.

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[1] Political Report of the VIII Party Congress, National Political Publishing House, 1996, p. 105.
[2] -ditto-, p. 189.
[3] National Political Publishing House, 2002, p. 120.

b) Developing biotechnology for the benefit of sustainable development of agriculture, forestry and fishery, as well as protection of human health and living environment.

c) Developing biotechnology on the basis of selectively perceiving and taking advantage of world achievements and in accordance with specific conditions in Vietnam; quickly approaching advanced biotechnologies (by creating a small and medium but advanced base) and at the same time modernizing traditional technologies.

The Resolution also identifies the objectives for biotechnology development in Vietnam by 2010 as follows:
a) Conducting research and widely applying scientific and technological achievements in the field of biotechnology in the world to facilitate the national economy as well as protect the people's health and living environment in a practical and effective way.

b) Establishing a developed biotechnology base that lay a firm foundation for production of various products for domestic consumption and export.

c) Establishing a proper structure of science and technology agencies and institutions operating in the field of biotechnology, which are capable of conducting R&D at an advanced level and creating new and advanced technologies for the benefit of the national economy.

To this end, the Resolution puts forward four fundamental guidelines:
1) To enhance endogenous strength of biotechnology in the country;

2) To implement measures and incentives aimed at promoting a developed biotechnology base in Vietnam;

3) To promote international cooperation; and

4) To increase investment in biotechnology development.

Coupled with guidelines and policies of the Party and State for biotechnology development, a legal system for biotechnology development and biosafety has been created in a relatively synchronous manner, namely, legal regulations on science and technology research (including biotechnology); establishment, conservation and development of genetic resources (including crop and livestock genetic resources); management of export-import of animals, plants and micro-organisms; management of plant protection drugs; quarantine of animals and plants, quarantine at border; management of food safety and hygiene; protection of rare and endangered animals and plants.

On January 20th 2003, Vietnam officially became member of the Cartagena Protocol on Biosafety. To fulfil its obligation to the Cartagena Protocol, Vietnam constructed the draft National Action Plan. The content of the Draft Plan focuses on strengthening legal and regulatory framework, promoting State management capacity, building research capacity, raising public awareness and enhancing international cooperation in biosafety. The Vietnamese Government strongly support biosafety-related R&D activities and give priority to facilitating and assisting the research and establishment of monitoring standards, methods and procedures, applied technologies and specialized equipment for biosafety.

B. Regulatory regime for biosafety

Many legal documents on biotechnology or relevant to biosafety were ratified and entered into force; these include Decree 199/1999/ND-CP (18 September 1999), the Law on Science and Technology (2000), Joint Circular 2341/2000/TTLT/BKHCNMT-BTC (28 November 2000) and Decree No.

81/2002/ND-CP (17 October 2002) directly addresses the issue of science and technology activities in general and biotechnology in particular. The former Ministry of Science, Technology and Environment (MOSTE) and Ministry of Finance (MOF) provide detail guides for the implementation of the Decree 119 to support legal framework on management of biotechnology.

The 1993 Law on Environment Protection provides that export-import of biotechnology and bio-products, animals and plants, gene sources and micro-organisms related to environment protection must be permitted by relevant line agencies and state management bodies on environment protection. The Government also promulgated Decree 11/2002/ND-CP on management of export-import activities and transit of animals, plants, wild animals, providing detailed regulations on export, import, re-export and re-import according to the schedule of wild animals and plants under the CITES Convention and the law of the S.R. Vietnam.

Regarding management of food safety and hygiene, there is a large amount of subordinate regulations (about 50) in this field. They are, amongst others, Circular 04/1998/TT-BYT dated 23 March 1998 of the Minister of Health guiding the implementation of management of food safety and hygiene in trade, services and culinary service; Decision 2418/QD-BYT dated 18 December 1996 of the Minister of Health introducing "the Regulation on food quality registration"; Decision 867/QD-BYT dated 04 April 1998 of the Minister of Health introducing the List of food hygiene standards; Directive 08/1999/CT-TTg dated 15 April 1999 of the Prime Minister on enhancement in the quality of food safety and hygiene. In spite of the above legal strengthened base, concerned Ministries, agencies and local authorities have not coordinated in an effective and close manner and therefore difficult to fulfil their state management of food safety and hygiene in food production, commercialization, service, culinary enterprises.

In August 2005, the Prime Minister issued Decision No 212/2005/QD-TTg on "Regulation of biosafety management to genetically modified organisms, goods and products originated from GMO" (see Annex 5). This decision covers scientific research, technology development, production, trading and usage, import, export, transportation of GMOs and related products. It also considers the risk control and granting of biological safety certificates to such organisms and products.

The regulations specify that scientific research and development of technology on GMOs, and related products should be registered with the Ministry of Science and Technology and relevant ministries and agencies. The decision takes effect 15 days after publication in the Government's official gazette.

Under NAPB, a following actions should be developed to strengthen the legal framework:

- Incorporating biosafety in the Law on Biodiversity
- Formulating and promulgating the Government Degree on biosafety management of GMOs and the products thereof
- Formulating regulations on biosafety management by sectors
- Establishing regulations governing environmental impact assessment of GMOs and their products
- Establishing legal regulations on import and export GMOs
- Establishing regulations on management of production and trade of GMOs and their products

C. System for handling request for permits

In order to establish a efficient system for handling request in Vietnam, the Draft of NAPB clearly defines functions and responsibilities of relevant ministries/agencies in biosafety.

The Draft defines MONRE to be the National Focal Point for the Biosafety Clearing House (BCH), taking responsibility for receiving and exchanging related information on GMOs. In collaboration with MONRE, other National Competent Authorities inlcude:

- The Ministry of Agriculture and Rural Development (MARD) is responsible for management of GMOs and their products that are used in agricultural and forestry sectors;
- The Ministry of Industry (MOI) is responsible for management of GMOs and their products that are used in the industrial sector;
- The Ministry of Fisheries (MOFI) is responsible for management of GMOs and their products that are used in the fishery sector;
- The Ministry of Health (MOH) is responsible for management of GMOs and their products that are used in health, foodstuff and cosmetics.

The competent national authorities will:

- Receive notification of proposed transboundary movement of a GMO that falls within the scope of the Advanced Informed Agreement procedure (Article 8 of the Protocol);
- Acknowledge receipt of the notification (Article 9);
- Request further information from the notified, if necessary (Articles 9 and 10);
- Notify the decision of the Party of import to the notifier and the Biosafety Clearing-House (with reasons where required) (Article 10(3));
- Respond to requests by the Party of export or notifier to review decisions (Article 12);
- Consult with the notifier, if necessary, on treatment of confidential information (Article 21).

Biosafety is a new issue that requires not only biosafety managers to acquire professional skills and modern biotechnology knowledge but also an appropriate base for them to conduct research and field trial to get sufficient information before making decision on biosafety.

Biosafety management capacity of the national focal point or competent national authorities in biosafety should be strengthened in order to meet the given requirements. In the short term, a study should be carried out to make overall assessment of capacity-building needs for the national focal point or competent national authorities in biosafety, including those for human resources, infrastructure, and other conditions for biosafety management implementation, i.e. decision-making, monitoring and assessment. According to NAPB, capacity building should be promoted through following activities:

a) Education and training of professional staff in charge of biosafety;

b) Study tours to learn safety management experiences in foreign countries;

c) Infrastructure building for monitoring and assessment of biosafety; and

d) Establishment of coordination mechanism amongst concerned Ministries and agencies in biosafety management.

D. Systems for monitoring of environmental effects and enforcement

Vietnam has already got a system environmental impact assessment (EIA) which supervises the adverse impact of building, trading and economic activities on environment.

The biosafety monitoring will be implemented by incorporating in the existed system for environmental impact assessment (EIA). Based on these assessments, effective measures will be taken to prevent or minimize adverse effects. The biosafety monitoring system consists of the following contents:

- Source analysis helps to identify factors affected by GMOs such as reproduction capacity and gene transference to other organism.
- Assessment of status quo or recipient organism provides some information relating to each individual, population, biological groups and ecosystem, as well as information on soil, water and air, and factors that may be affected by GMOs. This information includes possibly affected objectives, expression, and life or evolution cycles of recipient organism.
- Impact forecast comprises descriptions of impact process and its outcomes. The process will analyze GMOs impacts posed to recipient organisms or protection objectives.
- Uncertainty analysis is a kind of danger assessment that considers and weighs the possibility of sudden and harmful risks.
- Environmental protection measures could be divided into two groups: prevention of gene dispersion and removal of remaining GMOs such as safe package of seeds; isolation to prevent external dispersion of genes, removal of remaining GMOs by burning, burying and other safe measures.

E. Public Information and participation

Biosafety is a relatively new issue for Vietnam. The awareness of the public on this issues is inadequate and inaccurate. So, the community must be informed adequately and accurately about biosafety issues such as GMOs, GMOs products and the safety of these products. To ensure that, the draft of Vietnamese NAPB addresses the following contents:

- Establishing a Biosafety Clearing House (BCH): One of the requirements posed to each Party to the Cartagena Protocol is to establish a National Biosafety Clearing House in order to ensure information exchange.

The main contents of establishing biosafety information system consist of:

  - Developing methods for collecting, recording, storing and exchanging biosafety data;
  - Preparing guide documents for management of biosafety data and information linkage;
  - Establishing a biosafety databank;
  - Establishing information sharing mechanism between the National Biosafety Clearing House and sectoral BCHs;
  - Establishing international information sharing mechanism; and
  - Establishing a biosafety information system to provide public assess to biosafety information.

- Developing and implementing a media program on biosafety which includes:
  - Preparing, editing and disseminating documentary films and TV serials on biotechnological issues (namely biotechnology's achievements, prospects, social impacts and challenges);
  - Publishing general knowledge textbooks about modern biotechnology and biotechnology; and
  - Organizing training courses, workshops and seminars on biosafety for all public target groups.
- Promoting public participation in biosafety-related decision-making

Biosafety management of GMOs and their products are best handled by public participation due to the close relationship between biosafety and public health. For that reason, promotion of public participation in biosafety-related decision-making is necessary and should focus on the following main actions:

  - Establishing a website on biosafety for pubic access and information exchange;
  - Establishing public groups participating in biosafety management;

- Conducting public hearings for decision-making process of use and management of GMOs and their products;
- Promoting public participation in detection, assessment and management of risks posed by GMOs and their products; and
- Introducing biosafety into school education. Vietnam has more than 24 million of pupils at all levels, accounting for around 30% of total population. It is the target group on which provision of information and awareness raising of biosafety must be focused.

Note: In 2006, Vietnam will implement the nBCH project under the UNEP-GEF supported Project for "Effective Participation in the BCH". This project will set up an nBCH and biosafety website. The BCH project will contribute to the overall goal of this project on capacity building for the implementation of the NBF, and complement component E on promoting public information and participation.

C2.C PROJECT Rationale

While demonstrating Vietnam's commitment to addressing the needs of biotechnology management, the policy and legislative framework falls short of achieving full management of export-import of biotechnology and bio-products, animals and plants, gene sources and micro-organisms due to ambiguities and gaps.

More significantly, the main actors in biotechnology and bio-products have a poor understanding of regulator regime for biosafety as well as the scope of rights under the laws or mechanisms contained in national legislation. Public awareness of the laws will need to be enhanced if the legislation is to serve as an effective tool for the safe use of biotechnology and their products.

In the absence of GEF contribution, the baseline scenario is as follows:

a. Implementation of Protocol

Biosafety in Viet Nam is a newly emerging priority issue. Though Vietnam successfully completed the GEF project "development of NBF", it stills lacks the capacities for biosafety management, including: risk assessment, decision-making, and risk management that are essential for implementing the Cartagena Protocol.

At this moment, Vietnam has identified a focal point and competent authorities for the Protocol. An Action Plan for Implementation the Cartagena Protocol has been formulated, setting out a series of priority actions for biosafety management to be carried out up to 2010. However, challenges for implementation of the plan include operationalising the legal framework, putting in place systems for handling applications for research, field-testing, commercialization, utilization, import and export of GMOs and their products; clear distribution of responsibility amongst ministries; having in place workable information systems for GMOs; putting in place workable systems for monitoring and enforcement; and strengthening of relevant human resources, equipment and facilities.

b. Economic situation

Vietnam has a population of 83.5 million peoples, among them 78% are living in rural areas. The economic contributions to GDP of agriculture, fishery and forestry are 26% (AFF), of industry 32.7% and of services 41.3%, respectively. In the contribution agriculture to GDP, plant cultivation produces 81.2%, livestock 16.3% and services only 2.5%. About 30 million tons of rice are produced on 7.3 million ha of land every year; in recent years, Vietnam has changed from being an importer of rice, to being the third largest rice exporter in the world. Thus agricultural production has assumed a very important role in economic development in Viet Nam and the country is likely to turn to increasing use of biotechnology in order to improve yields and production of important crops such as rice.

Therefore, food security, export orientation and rural development are assigned highest priorities in agriculture policies of Vietnam. The Strategy for Socio-Economic Development, 2001 – 2010 builds on these past achievements and sets out a series of specific national, sectoral, crosscutting and regional objectives. The emphasis is on maintaining high levels of GDP growth, on modernising and industrialising society, and on overcoming poverty in rural and urban areas. Thus biosafety and the safe use of biotechnology are likely be important considerations in the drive towards economic development.

As environmental protection cuts across all sectors, it is a responsibility of the society as a whole. The priority actions to achieve these strategic goals are elaborated in the 2001 – 2005 Five Year Socio-Economic Development Plan.

c. Environmental and Development Viewpoint

Two recently initiated programmes particularly related to capacity to manage the global environment are the Master Programme on Public Administration Reform for the Period 2001 – 2010 (MPPAR) and the Vietnam Agenda 21 process. The MPPAR was launched in mid-2001 with the objective of building a democratic, clean, strong, professionalized, modernised, effective and efficient public administration system. The programme covers legislative reform, organisational and functional reform, decentralisation, human resource development and salary reform.

In 2004, Prime Minister promulgated the Strategic Orientation for Sustainable Development in Vietnam (Vietnam Agenda 21), which are the legal foundations for ministries, sectors, localities, organisations and relevant individuals to follow during their implementation and co-operation activities in order to ensure the sustainable development in Vietnam in the 21st century.

PROJECT GOAL

The goal is to assist Viet Nam to have a workable and transparent national biosafety framework by 2010, to fulfil its obligations as a Party to the Cartagena Protocol on biosafety, and to comply with the country's Agenda 21, the government strategy on development of biotechnology (Resolution 18/CP), and the National Action Plan for biosafety (NAPB).

EXPECTED PROJECT OUTPUTS BY COMPONENT

Component A	**To assist Viet Nam to integrate and incorporate safe use of biotechnology into national sectoral action plans and strategies in conformity with the national Agenda 21.**
Outputs	1 Government recognises the importance of biosafety for sustainable development by approving the National Action Plan on Biosafety to 2010. 2 Biosafety action plan integrated into national sectoral plans and strategies for Biodiversity, environmental protection, Biotechnology, Agriculture, Fisheries, Trade, and Health.
Component B	**To strengthen the legal and regulatory framework on biosafety so that it is consistent with the Cartagena Protocol, workable and responsive to national needs and priorities.**
Outputs	1 A regulatory regime in place for management of GMOs. 2 Biosafety regulations formulated for GMO management in different sectors. 3 Biosafety regulations formulated and promulgated for trade in GMOs and their products.

Component C	**A workable system in place for handling requests, carrying out risk assessment, and decision making for GMOs.**
Outputs	1 A fully functional administrative system for handling requests for GMOs 2 A fully functional system for risk assessment. 3 A fully functional system for decision-making. 4 Capacity building for the safe development and use of biotechnology in Viet Nam.
Component D	**To set in place a workable and effective national system for monitoring and enforcement**
Outputs	1 Well-defined roles and responsibilities of NCAs for monitoring and enforcement established. 2 To strengthen national capacity for enforcement. 3 To establish and make operational emergency response procedures (ERP).
Component E	**To establish a workable and effective national system for public awareness, education and participation in decision making for GMOs.**
Outputs	1 A system for access to, and sharing of information, that is up and running 2 A strengthened system for public awareness on the safe use of GMOs.. 3 Strengthened system public participation in decision making on GMOs.

INDICATORS FOR EXPECTED OUTPUTS

Refer also to project logframe (Annex 1).

A. Integration of the safe use of biotechnology into national sectoral action plans and strategies

- Safe use of biotechnology included in national economic and social development plans (2006-10)
- NAPB supported by relevant government agencies by inclusion of biosafety in their sectoral development plans and strategies.
- The National Action Plan on Biosafety approved by Prime Minister.
- All relevant national action plans and strategies include biosafety as an issue relevant to their sector.

B. Regulatory Regime

- Biosafety incorporated into biodiversity law
- Decree on GMO management prepared
- Biodiversity law published in official gazette
- Regulations governing Biosafety published on BCH
- Regulations comply with Cartagena Protocol and ICCP checklist
- Sectoral Regulations promulgated by relevant Minister
- Sectoral Regulations published in gazette
- Sectoral Regulations published on BCH
- Trade related biosafety regulations published in official gazette
- Trade related biosafety regulations published on BCH

C. System for handling applications

- Clear definition of Roles and Responsibilities for functions related to GMO applications;
- Clear definition of Roles and Responsibilities for ERP, accidental release, illegal movement;

- Guidelines, manuals and procedures for handling all aspects of requests for GMOs prepared and made available for applicants and public;
- Percentage of GMO applications processed on time and according to established procedures;
- Risk assessment criteria for GMOs in Viet Nam prepared and made available to stakeholders;
- Risk assessment and management guidelines prepared and made available to all stakeholders;
- National roster of risk assessment experts prepared and made available to all NCAs;
- 1 reference laboratory able to carry out risk assessment according to established procedures;
- Percentage of GMO risk assessments carried out according to established national and international procedures;
- Clearly defined roles and responsibilities for NCAs for decision making on GMOs made available to all stakeholders;
- Clear guidelines for decision making on GMO applications prepared by NCAs and made available to all stakeholders;
- All NCAs able to make decisions on GMO applications according to national guidelines and on time;
- Percentage of decisions for GMO applications made with public consultation as defined in Cartagena Protocol Article 23(2);
- Summaries of all decisions on GMO applications published on BCH;
    - Numbers of scientific personnel in 1 reference laboratories able to carry out risk assessment;
    - Results of surveys on scientific manpower published by government;
    - Strategy for capacity building for GMO risk assessment approved and published by government.

D. Follow-up systems for Monitoring and Enforcement

- Clearly defined roles and responsibilities for NCAs and relevant government agencies for monitoring and enforcement;
- Percentage of staff with monitoring and enforcement responsibilities in NCAs and MONRE trained;
- Clear guidelines and procedures on M&E published by government and made available to stakeholders;
- Percentage of monitoring requirements for GMO decisions completed as per established procedures.
- Clearly defined roles and responsibilities for NCAs for enforcement of decisions on GMO applications;
- Percentage of staff in enforcement agencies completing legal training;
- Percentage of staff in enforcement agencies completing training in identifying potential illegal imports of GMOs;
- Clearly defined ERP roles and responsibilities for NCAs and other relevant government agencies;
- Procedures for emergency responses for GMOs prepared and made available to all relevant agencies;
- Percentage of staff in relevant agencies trained in handling emergencies to do with GMOs;
- Facilities for dealing with ERP are available in areas of GMO releases.

E. Systems for Public participation

- Percentage of stakeholders with access to information on GMOs;
- Number of times that Vietnamese biosafety website is accessed;
- Numbers of campaigns for raising public awareness on biosafety;

- Percentage of public showing awareness of biosafety in surveys of public opinion;
- Percentage of farmers showing awareness of biosafety and dangers of illegal imports of GMOs in surveys of farmers;
- Numbers of people participating in public meetings and debates on biosafety;
- Workable entry points for public participation and consultation identified in decision making system on GMOs;
- Numbers of NCA decision making bodies making specific provision for public representation on their decision making body;
- Number of people making public meetings on applications for GMO release into the environment;
- Percentage of applications receiving submissions or inputs from public;

ACTIVITIES AND FINANCIAL INPUTS NEEDED TO ENABLE CHANGES

Note: Details of capacity building activities are summarised in Table 1).

Planned activities to achieve outputs

A. Proposed Activities for Integration of the safe use of biotechnology into national sectoral action plans and strategies

A1 Government recognises the importance of biosafety for sustainable development by approving the National Action Plan on Biosafety to 2010.

1) Provide briefing for PM & cabinet on biosafety as a sustainable development issue;
2) Prepare brief on costs and benefits of NAPB to identify synergies between development of biotechnology and sustainable use of biodiversity resources;
3) Awareness seminars for policy makers and planners on synergies between biosafety and biotechnology;
4) Consultations with relevant government agencies to review NAPB to ensure its compatibility with sectoral plans and strategies;
5) Peer review of NAPB by international experts to ensure its consistency with Cartagena Protocol;
6) Based on results of consultations and peer review, revise NAPB as necessary.

Costs in US$ (TOTAL:14,000; GEF contribution: 11,000; Government contribution: 3,000)

A2 Biosafety action plan integrated into national sectoral plans and strategies for Biodiversity, environmental protection, Biotechnology, Agriculture, Fisheries, Trade, and Health.

1) Carry out a series of awareness seminars on NAPB for policy makers and planners from sectoral government agencies;
2) Contract national consultants to carry out study of how biosafety fits into sectoral plans, based on an analysis of sectoral plans and NAPB;
3) Work with relevant ministries and agencies to review sectoral plans to identify how NAPB can contribute to sectoral priorities;
4) Brief science and technology policy committees on the contribution of NAPB to sectoral plans and strategies.

Costs in US$ (TOTAL: 55,000; GEF contribution: 42,000; Government contribution: 13,000;)

B. Proposed Activities for Regulatory regime

B1 A regulatory regime in place for management of GMOs.

1) Training for relevant personnel in international obligations and requirements of Cartagena Protocol, other MEAs, trade agreements, etc.
2) Based On NAPB, prepare a draft of biosafety provisions in the law on biodiversity;
   a) Consult with all relevant government agencies and stakeholders to ensure that proposed provisions are consistent with NAPB and objectives of biodiversity law;
   b) Finalise provisions for biosafety for inclusion in biodiversity law;

3) Formulate government decree on management of GMOs as set out in NAPB;
   a) Consult with all relevant government agencies and stakeholders to ensure that decree is consistent with national and sectoral priorities;
   b) Promulgate government decree on management of GMOs
4) Formulate regulations for EIA for GMOs and their products as set out in the NAPB (programme 1, action 4);
   a) Consult with all relevant government agencies and stakeholders on proposed EIA regulations for GMOs;
   b) Finalise and promulgate EIA regulations;

Costs in US$ (TOTAL: 25,000 ; GEF contribution: 12,000; Government contribution: 13,000;)

B2 Biosafety regulations formulated for GMO management in different sectors.

1) Study of examples of sectoral regulations/guidelines/experiences from other countries;
2) Provide training for relevant personnel in sectoral agencies on international obligations and drafting of appropriate regulations using international and/or regional experts;
3) Work with relevant government agencies to formulate draft sectoral regulations for management of biosafety for:

- Agriculture & forestry – for genetically modified plants, animals and micro organisms related to agricultural production and forestry.
- Fisheries - for genetically modified aquatic species for fisheries production;
- Food – for GMOs in food and food products, additives, and food maintenance;

4) Consult with all relevant government agencies and stakeholders on proposed sectoral regulations for GMOs, using international and/or regional experts for peer review;
5) Finalise and promulgate sectoral regulations for GMOs based on results of consultations.

Costs in US$ (TOTAL:76,000; GEF contribution : 63,000; Government contribution: 13,000)

B3 Biosafety regulations formulated and promulgated for trade in GMOs and their products.

As set out in Programme 1, Actions 4 and 5 of NAPB

1) Study of examples of experiences from other countries on regulation of in trade GMOs and their products;
2) Provide training for relevant personnel on international obligations and drafting of appropriate regulations using international and/or regional experts;
3) Work with relevant government agencies to formulate draft regulations for import and export of GMOs and their products to include specific provisions for import and export; Advanced notification; Safety monitoring and management in import-export process; Transit; Transport; Labelling requirements for commodities containing GMOs and their products; Investment activities; Damage compensation; and Dispute settlement procedures.
4) Consult with all relevant government agencies and stakeholders on proposed import and export regulations for GMOs;
5) Finalise and promulgate import and export regulations for GMOs based on results of consultations and expert advice.

Costs in US$ (TOTAL: 36,000; GEF contribution :34,000; Government contribution : 2,000)

C. Proposed Activities for Handling requests for permits

C1 A fully functional administrative system for handling requests for GMOs

Strengthening capacity of different National Competent Authorities (NCAs) and focal points for carrying out administrative tasks. This will include:

1) Capacity needs assessment for NCAs;
2) Training programme for NCAs on administrative tasks as identified by the assessment. This will include workshops, seminars, study tours, on-the-job training, etc;
3) Provide facilities for carrying out administrative tasks, including office equipment; Preparation of manuals and other documents setting out procedures for receipt and handling of applications;
4) Development of guidelines for handling of: Emergency responses; Accidental releases; Illegal movement of GMOs; Transit; Contained use; AIA and FFP; Handling and transport; Packaging; Labelling; Confidential information.
5) Identification of responsibilities of different NCAs for: Emergency responses; Accidental release; Illegal movement of GMOs; Transit; Contained use; AIA and FFP; Handling and transport; Packaging; Labelling; Identification of GMOs;

Costs in US$ (TOTAL: 160,000; GEF contribution: 95,000; Government contribution; 65,000)

C2 A fully functional system for risk assessment.

1) Based on NAPB Programme 3, Activity 5, carry out study on research and use of GMOs and their products in Viet Nam to identify lessons and best practices;
2) Based on NAPB Programme 3, Activity 2, carry out research to identify and establish risk assessment criteria for Vietnamese conditions;
3) As set out in Programme 3, Action 2 of NAPB, develop guidelines on risk assessment and management (using international experts and inter. Experts) based on:
   a) Study of existing risk assessment techniques in Viet Nam and other countries;
   b) Collection and study of relevant documents of concerned ministries and agencies;
   c) Specific techniques and procedures for risk assessment within the scope of different NCAs.
4) Strengthening capacity of different NCAs for risk assessment
   a) Assessment of existing capacity for risk assessment
   b) Capacity needs assessment
   c) Training programme for NCAs on risk assessment as identified by the assessment (workshop, study tours)
5) Identification of risk assessment experts for all NCAs;
6) As set out in NAPB Programme 3, Action 4, strengthen capacity of the 1 key laboratories for carrying out risk assessment based on:
   a) Conducting survey and evaluation of technical capacity of these key laboratories in risk assessment posed by GMOs and GM products;
   b) Preparing a capacity building plan for 1 selected laboratory to meet management requirements;
   c) Strengthening professional expertise for risk assessment in the 1 selected laboratory.
   d) Assessment of existing facilities for risk assessment in the 1 key laboratory;
   e) Providing equipment and facilities for risk assessment as needed for the 1 selected laboratories;
7) Assessment of existing contained use and field trial facilities for risk assessment for GMOs;
8) Strengthen existing contained use and field trial facilities for risk assessment based on gaps and needs identified by assessment.

Costs in US$ (TOTAL: 371,000; GEF contribution : 160,000; Government contribution: 211,000)

C3 A fully functional system for decision making.

1) Identify training needs for decision making in NCAs;
2) Strengthen capacity of different NCAs for decision making through:

- Training of decision makers, especially in international obligations;
- Development of national guidelines on decision making;
- Establishment of mechanisms for public participation in decision making;

- Definition of socio-economic priorities to be taken into consideration in decision making.

Costs in US$ (TOTAL: 74,000; GEF contribution : 61,000; Government contribution : 13,000)

C4 Capacity building for the safe development and use of biotechnology in Viet Nam.

1) Based on NAPB Programme 3, Action 1, evaluate R&D capacity in biotechnology and biosafety in the country and formulate a plan to strengthen this capacity.
2) Based on NAPB Programme 3, Action 6, develop and strengthen scientific manpower in biosafety research by:
   a) Conduct survey and assessment of the current status of scientific and technical manpower working in biotechnology and biosafety;
   b) Evaluating training needs through survey, investigation, and review conferences;
   c) Prepare plans for strengthening human resource capacity;
   d) Identify short and long-term training solutions;

Costs in US$ (TOTAL: 60,000 GEF contribution: 20,000; Government contribution : 40,000)

D. Proposed Activities System for follow-up (Monitoring of environmental effects, inspections and enforcement)

D1 Well-defined roles and responsibilities of NCAs for monitoring and enforcement (M&E) established.

1) Finalise survey of existing roles and responsibilities of NCAs and MONRE for monitoring;
2) Based on results, clearly identify roles and responsibilities of NCAs and MONRE for monitoring in the biosafety decree and in sectoral regulations;
3) Identify training needs of NCAs and MONRE for monitoring;
4) Provide capacity building for monitoring for NCAs and MONRE through:
   a) Training workshops on monitoring;
   b) On-the-job training for relevant personnel;
   c) Study tours for relevant personnel.
5) Provide guidelines, procedures and manuals for monitoring.

Costs in US$ (TOTAL: 30,000; GEF contribution : 20,000; Government contribution : 10,000)

D2 To strengthen national capacity for enforcement.

1) Carry out a survey of existing systems for enforcement of rules and regulations to identify gaps and needs;
2) Based on results of surveys:
   a) Develop appropriate regulations, guidelines, and procedures for enforcement;
   b) Provide legal training for relevant personnel in responsible agencies in enforcement (NCAs and MONRE).
   c) Provide training in identifying illegal GMO imports for border control agencies, including customs and quarantine, as well as NCAs.

Costs in US$ (TOTAL: 114,000; GEF contribution: 96,000; Government contribution: 18,000)

D3 To establish and make operational emergency response procedures (ERP).

1) Assign responsibilities to appropriate authorities and focal points for ERP in consultation with NCAs;
2) Develop guidelines, rules and regulations for ERP;
3) Define procedures for emergency responses;
4) Provide training in ERP for both decision makers and on-the-ground personnel in ERP;
5) Ensure adequate provision and maintenance of equipment and facilities necessary for dealing with emergencies.

Costs in US$ (TOTAL:30,000; GEF contribution : 20,000; Government contribution : 10,000)

E. Proposed Activities for Public information, participation, awareness

E1 *A system for access to, and sharing of information, that is up and running.*

1) Development of training materials, including manuals, procedures and other documentation for information sharing;
2) Development and dissemination of outreach materials on access to information (newsletter, etc);
3) Training workshops for stakeholders on how to access biosafety information;

Costs in US$ (TOTAL: 60,000; GEF contribution : 40,000 Government contribution :2 0,000)

E2 *A strengthened system for public awareness and education on the safe use of GMOs..*

1) Identify relevant government agencies for managing public and specific target group awareness programmes;
2) Training for relevant staff of NCAs and other government agencies in awareness raising activities;
3) Production and dissemination of awareness raising materials for general public and for specific target groups such as farmers and consumers;
4) Awareness seminars, workshops, debates and meetings for specific target groups, such as farmers, minority peoples, and consumers, on importance of biosafety;
5) Prepare and disseminate documentary films and TV serials on biotechnological issues (namely biotechnology's achievements, prospects, potential environmental and social impacts and challenges);

Costs in US$ (TOTAL:104,000; GEF contribution :75,000; Government contribution :29,000)

E3 *Strengthened system public participation in decision making on GMOs.*

1) Identify and institutionalize entry points for public participation in decision-making on GMOs;
2) Develop mechanisms for public involvement in biosafety management;
3) Training for NCA staff on facilitating public participation into decision making on GMOs;
4) Training workshops for stakeholders on how to contribute to decision making on GMOs.

Costs in US$ (TOTAL: 30,000 GEF contribution : 20,000; Government contribution :10,000)

Note on the relationship between the NBF implementation and BCH projects

The BCH project will focus on the following capacity building activities in order to ensure that Viet Nam is able to fulfil the requirements of the Cartagena Protocol with respect to the BCH:

- Identification of roles and responsibilities for handling, storing and exchanging information including the use of the BCH;
- Development of guidelines for the management of the information and compliance with BCH obligations;
- Training for government agencies on the use of the BCH, including inputting data and accessing information;
- Development of the nBCH and biosafety website, to enable NCAs, related institutions, and stakeholders to access and exchange biosafety information;
- Connection to the global BCH for exchange of information on biosafety at global level.

These BCH project activities will be carried out **concurrently with the NBF implementation project and will complement** the following activities under Output E1 of this project:

- Development of training materials, including manuals, procedures and other documentation for information sharing;
- Development and dissemination of outreach materials on access to information (newsletter, etc);
- Training workshops for stakeholders on how to access biosafety information;

Note: Additional crosscutting costs for project management and coordination are summarised in table 6, and for equipment and operating costs in table 7.

Table 1: In-country Training Summary[2]

Subject	Output	Duration	Number of participants	Type of participants	Expert requirements	Costs	Total cost US$
Awareness seminars on Cartagena Protocol, synergies between biosafety and biotechnology	A1 & A2	8 x half-days	30-40 at each	policy makers and planners	1 or 2	$3,000 per seminar + consultant costs	24,000
a. Cartagena Protocol b. MEAs – CBD, etc c. Trade related agreements	B1 to B3	2 x 2 days	30 people for each course	Lawyers Policy-makers Scientists, etc	1 to 2	$7k per workshop + consultant costs	14,000
Handling applications and decision making on GMOs	C1 & C3	3 x 2 days	30 people for each course	Officials and scientific personnel for national competent authorities	1 or 2	$7k per workshop + costs of consultant	21,000
Risk assessment and management	C2	3 x 2 days	30 people for each course	Officials and scientific personnel for national competent authorities	2-3	$7k per workshop + costs of consultant	21,000
Monitoring, QA for detection of GMOs	D1, D2,	3x5 days	20 people for each course	Scientific officers, inspectors, and assistants from NCAs	2-3	$10k per workshop + costs of consultant	30,000
Enforcement of GMO regulations	D2	3x2 days	30 people for each course	inspectors, and assistants from NCAs	2-3	$7k per workshop + costs of consultant	21,000
Training in awareness raising	E2	2x1 day	50 people for each course	Officials and scientific personnel for national competent authorities	National only	$5k per workshop	10,000
Awareness seminars on biosafety for specific stakeholders	E2	10x1 day	50 people per course	Farmers, extension workers, consumers	National only	$2k per seminar	20,000
						TOTAL	**166,000**

Table 2: Overseas Training – study tour summary

Output.	Subject	Duration	Participants	Number of Participants	Location	Total (US$)
C1 and C3	Handling applications and decision making on GMOs	2 weeks	Officials and scientific personnel for national competent authority	6	2 countries – one developed and one developing:	20,000
C2	Risk assessment and management	2 weeks	Officials and scientific personnel for NCAs	6	2 countries – one developed and one developing:	20,000
D1 and D2	a. Identification and detection of GMOs; b. Quantification and determination of the content of GMOs in non-GMOs and their products c. Quality Assurance in the analysis on GMOs	3 weeks	Scientific officers & Inspectors from NCAs and GMO Lab	6	2 countries – one developed and one developing:	25,000
	Total					65,000

[2] The awareness and training seminars will build on the capacity building activities of the NBF Development project, bringing in a wider target group, more in-depth training, and an increasing focus on issues that are relevant to implementation of the NBF.

C.3 Sustainability

Viet Nam faces many challenges in fulfilling its obligations to the Cartagena Protocol. By assisting Vietnam to have a workable and transparent National Biosafety Framework in place by 2010, this project will not only enable Viet Nam to meet its obligations under the Cartagena Protocol, but will also promote the sustainability of the systems established under the NBF.

To overcome the challenges faced by Viet Nam, project activities will focus on building capacity within the country on developing and implementing policy, strengthening the regulatory regime, strengthening systems for handling request for permits, follow-up and public participation. All these activities will be carried out in order to make long-term impacts in the following areas:

- **Institutional and operational** terms: the project will strengthen institutional aspects on biosafety, including building capacity for focal point and national competent authorities (NCA) in biosafety management, and developing a workable system for follow-up, risk assessment and handling requests. Through the capacity building activities, the project will also aim to strengthen cooperation and coordination between different government agencies, as well as promoting public awareness and participation in decision-making on GMOs. When focal point and NCAs have been strengthened, they themselves can manage and deal with biosafety issues after the project ending.

Furthermore, project will help to develop a legal framework, which clearly defines functions and responsibilities of relevant institutions/ministries on biosafety, provides provisions for GMO management, commercialising GMOs and their products. The legal framework will facilitate Vietnam's ability to fulfil its obligations to the Cartagena Protocol.

- **Financial and political** terms: the most significant activity that the project will carry out will be to make Government recognize the importance of biosafety for sustainable development by approving the National Action Plan on Biosafety through 2010. Also, it will help to make the Biosafety Action Plan integrate into the national sectoral plans and strategies for Biodiversity, Environmental Protection, Biotechnology, Agriculture, Fisheries, Trade and Health. The project also aims to enhance the awareness of Government, organisations and individuals. As a result, the interest of these institutions and individuals in biosafety will increase greatly. Government will also recognise the importance of biosafety and invest more on this area.

The increased interest and recognition of the importance of biosafety by government will stimulate further investment from government in biosafety, as well as from different donors. The project activities will also promote the financial sustainability of the systems for handling GMO applications by exploring and putting in place "fees-based" or "user-pays" financial mechanisms to complement investment by government and budgetary allocations for recurrent costs of implementing the NBF.

C. 4 Replicability

1. This project is a "national executed" project that promote the role of the recipient country in developing and implementing project activities. Experiences gained from the project implementation, particularly in terms of project management, coordination of activities of different agencies, promoting public participation in developing policies and in decision making, and ensuring that scientific development goes hand-in-hand with efforts in raising public awareness and education, will benefit and inform the development of public policies and processes in other areas of government endeavours, including science and technology R&D.

2. The lessons and best practices gathered from project implementation will be shared with other countries through regional meetings, exchanges of personnel and networking between those involved in biotechnology and biosafety.

3. The experiences of the project will be disseminated by posting regular reports on the progress of the project on the website on biosafety (which will be set up under the BCH project), and by ensuring that results of risk assessment decisions are also posted on the BCH. In addition, project staff will participate actively in regular meetings of personnel from NBF projects from Asia as well as from other regions.

4. The detailed Monitoring and Evaluation plan to be developed at the inception of the project will include indicators to measure potential of replication.

C. 5 Stakeholder involvement

In which, Ministry of Natural Resources and Environment is responsible for presiding over and coordinating with the concerned ministries, agencies and other organizations at central level; UNEP/GEP will be main sponsor for the project.

1. Stakeholder identification

Biosafety is a cross-cutting issue, which relates to several sectors, including ministry of Natural resources and environment, ministry of agriculture and rural development, ministry of Health, Ministry of Fishery, ministry of science and technology, ministry of industry, ministry of trade, ministry of Planning and Investment, Office of Government, General office of customs. Some other institutes and community-based organizations are also relevant to this issue, such as biotechnology institute, consumer association. These stakeholders were identified during the NBF development project.

2. Stake holders participation:

All identified stakeholders were involved in designing the project, through stakeholder meeting to discuss on components of project, giving comment on draft of proposal.
Once the project is approved, stakeholders will be involved in carrying out project activities, including researching, taking part in workshops, seminars and others.
This project will also promote public participation in decision making on GMOs. by ensuring that mechanisms for public involvement in biosafety management are developed as part of component C.

3. Information dissemination and consultation:

A information sharing mechanism will be set up among ministries and relevant stakeholders. All project information will be posted on the website on biosafety. . The national coordinating committee will meet at Quarterly intervals to discuss on progress of the project. All findings and information of project will be disseminated.

Table 3: Major Stakeholders and their Participation

STAKEHOLDERS	Type of involvement
Parliamentarians, decision-makers	Representative of Office of Government will take part in National Coordinating Committee. Decision-makers will be invited to take part in workshops, seminars, meetings and will received awareness materials of the project.
Ministries Ministry of Natural Resources and Environment (MONRE); Ministry of Science and Technology (MOST); Ministry of Agriculture and Rural Development (MARD); Ministry of Fisheries (MOFI); Ministry of Health (MOH); Ministry of Planning and Investment (MPI); Ministry of Trade (MOT); Ministry of Finance (MOF)	Ministries are involved in carrying out project activities. A national coordinating committee (NCC) set up consists of representatives from relevant ministries. This committee will coordinate and supervise implementation of project.
Scientific community (including academic institutions): Biotechnology Institute and Institute for Agricultural Genetics	Providing service on formulation of the implementing regulations and rules, manuals and training guidelines.
Provincial People's Committees; IUCN, FAO in Hanoi Other civil-based organisations (Consumer association, farmer association, woman association.	Will be involved in activities on awareness raising and capacity building.

C6. MONITORING AND EVALUATION PLAN

The monitoring of the progress of project activities will be undertaken in accordance with UNEP's internal guidelines for project monitoring and evaluation. In this respect, self-evaluation will be ongoing throughout the project and GEF/UNEP's requirements of quarterly and half-yearly reports on substantive and financial matters will be provided. This will include a mid-term assessment (desk review) and end-of-project assessment undertaken by external review teams arranged by UNEP. Deliverables will be identified on a timetable agreed between UNEP and each participating country, and country-specific final reports will be prepared at the end of the activities foreseen by this project.

Project execution performance, delivered outputs and project impact will be measured according to the indicators developed in the project log frame (Annex 1). The general and specific objectives of the project and the planned outcomes (see logframe), provide the basis for this monitoring and evaluation plan The project co-coordinator, with the assistance of the NCC, will be in charge of monitoring and evaluation for the project and will take action whenever needed so as to guarantee that the M&E activities of the project and related indicators adequately reflect the needs of the project.

The project logframe, Annex 1, provides details of indicators for monitoring and means of verification of these indicators.

A detailed Monitoring and Evaluation Plan, based on the project logframe, will be prepared at the start of project implementation and include indicators for monitoring of project activities, effectiveness, and impact, as well as defining roles and responsibilities of the national project coordinator, the NCC and the UNEP Regional Coordinator in M&E. In summary, these M&E roles will include:

- **Monitoring of project implementation (inputs and activities)** – will be carried out by the NPC, the NEA under the oversight of the NCC, which will meet at regular intervals (quarterly).
- **Monitoring of progress** – will be done at the national level by the NCC, which will meet quarterly. The NPC and the NEA will submit six-monthly progress and financial reports to the UNEP biosafety Regional Coordinator, who will monitor project progress against the indicators listed in the logframe (annex 1).
- **Effectiveness of outputs** – will be monitored at the national level by the NCC, and at the regional level by the Regional Coordinator, based on the indicators listed in the logframe (annex 1).
- **Impacts of the project** – will be evaluated through a mid-term project evaluation.

Monitoring of performance and deliverable outputs
Monitoring of the project's execution for checking efficiencies and improve effectiveness of the project's implementation will be carried out on a regular basis to track the indicators as follows in Table 4:

Table 4: Indicators and means of their verification

Indicator	Verification
Quality half-yearly reports on progress and financial implications are prepared in time	Report received and verified by UNEP-GEF
Yearly project implementation review reports are prepared on time and of acceptable quality	Report prepared and submitted to UNEP-GEF
Performance targets are achieved in accordance with the project plan	Half-yearly reports submitted to UNEP-GEF
Any deviations from the work plans are explained and adjustments made to work plan	Deviation implications are reported in half-yearly or yearly reports as appropriate
Audit reports and reviews include indications of sound financial management	Audit statements are includes in appropriate reports
Steering committee tracks project progress and provides guidance	Minutes of steering committee deliberations included in appropriate reports
Steering committee provides guidance on project's progress and impact	Minutes of steering committee deliberations included in appropriate reports

It is expected that monitoring and evaluation of the project's progress will continue throughout the life of the project and NCC will be providing oversight including feedbacks and lessons learnt from other jurisdictions including the BCH. In addition, special attention will be given to the risks associated with the project management and focus on the following components (Table 5).

Table 5: Project management components

Component	Activity
Management structure	Monitor that responsibilities are clearly understood
Work flow	Verify that the project is maintaining its proposed work plan as assessed by the reporting framework
Co-financing	Ensure that disbursements happen on time and without complications
Implementation	Verify that work on project implementation is progressing as planned
Budget and financial management	Verify that work is progressing according to budget plans and that expenditures are in accordance with the project plan expectations
Reporting	Ensure that work progress is reported comprehensively and on time with critical analysis included
Stakeholder involvement	Ensure that all stakeholders are involved throughout the project
Communication	Ensure that communication within and between those involved in the project is open and frequent
Leadership	To ensure that project meets its needs (both short and long term) without compromising quality
Political influence	Ensure that the project continue to meet political expectations

Project implications

In accordance with the logframe, project's progress in achieving its outcomes will be continuously monitored and progress included in regular reports. The full operationalisation of the NBF (legal system, administrative system, system for monitoring of environmental effects, etc.) will represent the most important tangible output of the project and will be the main target for assessing project's success. In respect of monitoring and reporting, the following responsibilities are identified for the national executing agency and the coordinating committee.

The national executing agency is to:

- Prepare half-yearly and annual progress and financial reports (progress and financial) for UNEP, with supporting documentation as appropriate.
- Carry out a programme of regular visits and checks of activities in progress and pay special attention to those activities requiring special attention.

The national coordinating committee is to:

- Meet at least half-yearly and receive progress and financial reports, annual summary progress reports and all substantive reports and outputs and use them to review the progress of work in the project as a whole.
- Advise on implementation problems that emerge, and on desirable modifications to the work-plan.
- Monitor progress of the project, and advise on steps to improve it.

It is proposed that the reports shall have the following components included.

- Reports will use standard UNEP progress report format.
- A consolidated summary of the half-yearly reports will be included.
- The project logframe will be attached to each report and progress reported against outcome and output indicators.
- Review of delays and problems, and of action proposed to deal with these.
- Audit of accounts for project management and expenditures.

D FINANCING

D1. Incremental cost assessment

Table 6 provides a summary of baseline and incremental costs by output/component as well as information on GEF financing and national co-funding. The **total baseline expenditure** amounts to **US $ 400,000**, with main components related to integration of biosafety into national plans and strategies (US$ 15,000), biosafety legislation (US$ 20,000), handling of requests (US$ 150,000), monitoring and inspection (US$ 100,000), public awareness and participation (US$ 50,000), Project coordination and management (US$ 50,000), equipment and operating ($15,000). The **total alternative costs** have been estimated at **US$ 1,634,800** and the **total increment** has been estimated at US $ **US$ 1,234,800**. The national contribution amounts to **US $ 637,000**: this includes the baseline costs of US$ 400,000 and a contribution of $237,000 to the incremental costs. The remaining incremental cost of US $ 997,800 is requested from GEF.

Table 6. Summary incremental cost analysis

Component	Baseline	Alternative	Increment	Cost to GEF (Global Benefit)	Co-financing (In-kind & cash contributions)
Integration of biosafety into national plans and strategies	15,000	69,000	54,000	53,000	16,000
Biosafety legislation	20,000	137,000	117,000	109,000	28,000
Handling of requests	150,000	665,000	515,000	336,000	329,000
Monitoring of environmental effects and inspections	100,000	174,000	74,000	136,000	38,000
Public awareness and participation	50,000	194,000	144,000	135,000	59,000
Project coordination and management	50,000	204,800	154,800	120,800	84,000
Equipment and operating costs	15,000	121,000	106,000	38,000	83,000
Technical support	0	70,000	70,000	70,000	0
Total	**400,000**	**1,634,800**	**1,234,800**	**997,800**	**637,000**

D2. BUDGET

The detailed budget of the project is shown in Annex [2]. A summary of the budget by components with co-financing details (Table 7), staff costs (Table 8) and equipment and operating costs (Table 9) are given below.

Table 7: Project Budget by Components.

No	Component	GEF (US $)	Government (US $)	Total (UD $)
1	Biosafety policy	53,000	16,000	69,000
2	Regulatory regime	109,000	28,000	137,000
3	Handling applications	336,000	329,000	665,000
4	Monitoring and Inspection	136,000	38,000	174,000
5	Public participation and information	135,000	59,000	194,000
6	Project coordination	120,800	84,000	204,800
7	Equipment and operating costs	38,000	83,000	121,000
8	Technical support	70,000	0	70,000
	TOTAL	**997,800**	**637,000**	**1,634,800**

Table 8: Staff costs – not directly linked to a specific activity

Personnel	GEF	National Co-financing	TOTAL
National Project Director	14,400	24,000	38,400
National Project Coordinator	38,400	0	38,400
Financial Officer	24,000	0	24,000
Administrative officer	24,000	0	24,000
NCC travel and per diem	20,000	60,000	80,000
Total	120,800	84,000	204,800

Equipment and operating costs:
Office equipment and operating costs (US $ 116000) cover the purchase of computers, software upgrades, maintenance etc. as well as office utilities, stationery, and communication costs. This amount is shared between GEF and the country US$ 116,000 (see table 7).

Table 9: Equipment and operating costs

Items	GEF	National Co-financing	TOTAL
Project office equipment and maintenance	8000	13000	21000
Office supplier	10000	60000	70000
Communication cost	10000	10000	20000
Audit	5000	0	5000
Contingency	5000	0	5000
Total	**38000**	**83000**	**121000**

D3 PROJECT IMPLEMENTATION PLAN

The project will be carried out over four years. The implementation plan is provided in Annex [3].

E - INSTITUTIONAL COORDINATION AND SUPPORT

E1 CORE COMMITMENTS AND LINKAGES

This project builds on an UNEP's portfolio of enabling activities in over 123 countries and 8 demonstration projects out of 12, on capacity building for the implementation of the CP-carried out through the development and implementation of National Biosafety Frameworks respectively. This reflects UNEP's considerable experience and expertise in the area and therefore its comparative advantage in the field.

This portfolio has already produced relevant results, generated lessons learned and best practices being used /which can be used in other countries of the world. In this respect, the project will benefit from UNEP's experience and expertise to develop a fully operational NBF in Vietnam, where best practices and lessons learned will add to those being acquired through the eight demonstration projects currently running under UNEP.

E2. CONSULTATION, COORDINATION AND COLLABORATION

E2.a National Executing Agency

Vietnam Environment Protection Agency, which is the focal point to the Cartagena protocol on Biosafety, will be the National Executing Agency for this project. This agency will work on behalf of Vietnam's Government to manage the project, ensuring that its objectives will be met by the end of the project. The Agency will also provide the necessary scientific, technical, financial and administrative support to the project, working in close co-operation with relevant government agencies, the scientific community and the public and private sectors.

E2.b National Co-ordinating Committee

The National Co-ordinating Committee (NCC) will be established by the National Executing Agency (NEA) to advise and guide the implementation of the National Biosafety Framework. This committee will include representations of all government agencies with mandates relevant to the Cartagena Protocol on Biosafety and will include representations from the private and public sectors. This Committee will be multi-disciplinary and multi-sectoral in fields relevant to the Cartagena Protocol on Biosafety. The NEA may also establish sub-working groups as necessary with clear Terms of Reference as appropriate. The Terms of Reference (TOR) for the NCC are in Annex 6.

E2.c National Project Co-ordinator

The National Project Coordinator will be appointed by the National Executing Agency, after consultation with UNEP, for the duration of the National Project. The National Project Coordinator shall be responsible for the overall co-ordination, management and supervision of all aspects of the National Project. He/she will report to the National Co-ordinating Committee and UNEP, and liaise closely with

the chair and members of the National Coordinating Committee and National Executing Agency in order to coordinate the work plan for the National Project. He/she shall be responsible for all substantive, managerial and financial reports from the National Project. He/she will provide overall supervision for any staff in the NBF Team as well as guiding and supervising all other staff appointed for the execution of the various National Project components. The Terms of Reference (TOR) for the NPC are in Annex 6.

E2.d UNEP Steering Coordination Committee

The Steering Committee provides guidance and direction to the implementation of the project. It is chaired by UNEP, and comprises representatives of the National Executing Agency, two other implementing agencies, the GEF Secretariat as well as FAO and UNIDO. However, whenever technical and scientific issues related to the imple mentation of the MSP are to be addressed, the representative of STAP as well as experts selected in their personal capacity will be invited to participate. The Steering Committee will meet once a year and communicate mainly by e-mail and phone.

ANNEXES (after page 30)

ANNEX [1]	Project logframe
ANNEX [2]	Detailed Project Budget
ANNEX [3]	Implementation Plan
ANNEX [4]	Draft TOR for the National Executing Agency, National Project Committee, National Project Coordinator (see attached draft)
ANNEX [5]	DECISION No 212/2005/QD-TTg of August 26, 2005, Promulgating the Regulation on Management of Biological Safety of Genetically Modified Organisms, Products and Goods Originating from Genetically Modified Organisms.

TABLES

Annex 1: Logframe for Viet Nam NBF implementation project

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
COMPONENT: A. POLICY				
OBJECTIVE A: To assist Viet Nam to integrate and incorporate safe use of biotechnology into national sectoral action plans and strategies in conformity with the national Agenda 21.	Safe use of biotechnology included in national economic and social development plans (2006-10) All relevant national action plans and strategies include biosafety as an issue relevant to their sector.	- Strategies and action plans published in national official gazette, in other national media. ▪ National economic and social development plans (2006-10) published by government. ▪ Progress reports to UNEP; ▪ Mid-term evaluation ▪ End-of-project evaluation	- Government gives greater priority to biotechnology than to biosafety; - Biosafety not integrated into country's development planning; - Biosafety not integrated into sectoral plans and policies	- Briefing for PM and Cabinet on biosafety as a sustainable development issue; - Awareness raising for decision-makers on biosafety; - Briefing for sectoral committees on importance of biosafety as a sustainable development issue.
OUTPUT A1				
Government recognises the importance of biosafety for sustainable development by approving the National Action Plan on Biosafety to 2010.	The National Action Plan on Biosafety approved by Prime Minister.	- Agreed biosafety action plan published in national official gazette, in other national media, and the BCH. ▪ Progress reports to UNEP; ▪ Mid-term evaluation	- Government unaware of the synergies between biosafety and biotechnology; - All stakeholders not aware of benefits of biosafety; - NAPB not consistent with Cartagena Protocol;	- Briefings for government on biotechnology and biosafety; - Awareness seminars on biosafety for stakeholders; - Peer review of NAPB by international experts.
Proposed activities Provide briefing for PM & cabinet on biosafety as a sustainable development issue; Prepare brief on costs and benefits of NAPB to identify synergies between development of biotechnology and sustainable use of biodiversity resources; Awareness seminars for policy makers and planners on synergies between biosafety and biotechnology; Consultations with relevant government agencies to review NAPB to ensure its compatibility with sectoral plans and strategies; Peer review of NAPB by international experts to ensure its consistency with Cartagena Protocol; Based on results of consultations and peer review, revise NAPB as necessary.				
OUTPUT A2				
Biosafety action plan integrated into national sectoral plans and strategies for Biodiversity, environmental protection, Biotechnology, Agriculture, Fisheries, Trade, and Health.	NAPB supported by relevant government agencies by inclusion of biosafety in their sectoral development plans and strategies.	- Published National development plans include biosafety as a priority. - Biosafety action plan integrated into relevant sectoral plans and strategies by government agencies; ▪ Progress reports to UNEP; ▪ Mid-term evaluation	- Lack of awareness amongst decision-makers about importance of biosafety for sectoral plans and policies; - Lack of information about impacts of biosafety on different sectors.	Awareness seminars for decision-makers from different sectors; Research on synergies between biosafety and different sectors;

Annex 1: Logframe for Viet Nam NBF implementation project

Proposed activities Carry out a series of awareness seminars on NAPB for policy makers and planners from sectoral government agencies; Contract national consultants to carry out study of how biosafety fits into sectoral plans, based on an analysis of sectoral plans and NAPB; Work with relevant ministries and agencies to review sectoral plans to identify how NAPB can contribute to sectoral priorities; Brief science and technology policy committees on the contribution of NAPB to sectoral plans and strategies.				
COMPONENT: B. REGULATORY REGIME				
OBJECTIVE B: To strengthen the legal and regulatory framework on biosafety so that it is consistent with the Cartagena Protocol, workable and responsive to national needs and priorities.	Biosafety incorporated into new biodiversity law; Biosafety law and Regulations comply with Cartagena Protocol, ICCP checklist, and trade related obligations	▪ Biodiversity law, including biosafety provisions, promulgated in official gazette ▪ Biodiversity law, including biosafety provisions, published on the BCH ▪ Progress reports to UNEP; ▪ Mid-term evaluation ▪ End-of-project evaluation	- Biosafety decree not incorporated into biodiversity law; - Lack of clarity about regulation of biosafety in different sectors; - Lack of clarity about how biosafety regulations impact on trade.	- Biosafety decree incorporated into biodiversity law and promulgated by government; - Biosafety guidelines prepared and promulgated for different sectors; - Regulations on trade in GMOs and their products prepared and promulgated.
OUTPUT B1 A regulatory regime in place for management of GMOs.	Decree on GMO management approved by Prime Minister Biosafety incorporated into biodiversity law Biosafety Regulations comply with CP and ICCP checklist	▪ Decree on GMO management promulgated in official gazette ▪ Biodiversity law, with biosafety provisions, promulgated in official gazette ▪ Regulations governing Biosafety published on BCH ▪ Progress reports to UNEP; ▪ Mid-term evaluation	- Lack of capacity on implications of the Cartagena Protocol for Viet Nam; - Biosafety decree not accepted by government as a law; - Lack of support for biosafety decree amongst stakeholders.	- Training for relevant personnel on Cartagena Protocol; - Incorporate Biosafety decree into biodiversity law; - Consult with stakeholders on impacts of biosafety decree and regulations.

Annex 1: Logframe for Viet Nam NBF implementation project

Proposed activities Training for relevant personnel in international obligations and requirements of Cartagena Protocol, other MEAs, trade agreements, etc. Based On NAPB, prepare a draft of biosafety provisions in the law on biodiversity; Consult with all relevant government agencies and stakeholders to ensure that proposed provisions are consistent with NAPB and objectives of biodiversity law; Finalise provisions for biosafety for inclusion in biodiversity law; Formulate government decree on management of GMOs as set out in NAPB; Consult with all relevant government agencies and stakeholders to ensure that decree is consistent with national and sectoral priorities; Promulgate government decree on management of GMOs Formulate regulations for EIA for GMOs and their products as set out in the NAPB (programme 1, action 4); Consult with all relevant government agencies and stakeholders on proposed EIA regulations for GMOs; Finalise and promulgate EIA regulations;				
OUTPUT B2 Biosafety regulations formulated for GMO management in different sectors.	Sectoral regulations drawn up by relevant agencies Sectoral Regulations approved by relevant Minister Sectoral biosafety guidelines prepared by agencies	• Sectoral Regulations promulgated in official gazette • Sectoral Regulations published on BCH • Progress reports to UNEP; • Mid-term evaluation	- Lack of clear guidelines on biosafety for different sectors; - Poor support for biosafety amongst different sectors. - Lack of understanding of implications of biosafety for different sectors.	- Formulate sectoral guidelines in consultation with relevant sectors; - Capacity building for government staff on Cartagena Protocol implications for their sectors.
Proposed activities Study of examples of sectoral regulations/guidelines/experiences from other countries; Provide training for relevant personnel in sectoral agencies on international obligations and drafting of appropriate regulations using international and/or regional experts; Work with relevant government agencies to formulate draft sectoral regulations for management of biosafety for: Agriculture & forestry – for genetically modified plants, animals and microorganisms related to agricultural production and forestry. Fisheries - for genetically modified aquatic species for fisheries production; Food – for GMOs in food and food products, additives, and food maintenance; Consult with all relevant government agencies and stakeholders on proposed sectoral regulations for GMOs, using international and/or regional experts for peer review; Finalise and promulgate sectoral regulations for GMOs based on results of consultations.				

Annex 1: Logframe for Viet Nam NBF implementation project

OUTPUT B3 Biosafety regulations formulated and promulgated for trade in GMOs and their products.	Trade related biosafety regulations drafted by relevant agencies; Trade related biosafety regulations accepted by all government agencies; Trade related biosafety regulations approved by trade minister	• Trade related biosafety regulations promulgated in official gazette • Trade related biosafety regulations published on BCH • Progress reports to UNEP; • Mid-term evaluation	- Lack of clarity about regulation of trade in GMOs and their products in Viet Nam; - Government agencies not supportive of regulation of trade in GMOs &their products.	- Formulate regulations on trade in GMOs and their products in consultation with relevant government agencies; - Training for relevant government agencies on trade implications of GMOs.
Proposed activities Study of examples of experiences from other countries on regulation of in trading GMOs and their products; Provide training for relevant personnel on international obligations and drafting of appropriate regulations using international an d/or regional experts; Work with relevant government agencies to formulate draft regulations for import and export of GMOs and their products to include specific provisions for import and export; Advanced notification; Safety monitoring and management in import-export process; Transit; Transport; Labelling requirements for commodities containing GMOs and their products; Investment activities; Damage compensation; and Dispute settlement procedures. Consult with all relevant government agencies and stakeholders on proposed import and export regulations for GMOs; Finalise and promulgate import and export regulations for GMOs based on results of consultations and expert advice.				
COMPONENT: C. HANDLING REQUESTS				
OBJECTIVE C: A workable system in place for handling requests, carrying out risk assessment, and decision making for GMOs.	o Percentage of GMO applications processed on time and according to established procedures; o All NCAs able to make decisions on GMO applications according to national guidelines and on time; o Percentage of decisions for GMO applications made with public consultation as defined in Cartagena Protocol Article 23(2); o Summaries of all decisions on GMO applications published on BCH; -	• Statistics published by NCAs on GMO applications; • Records of applications and decisions published on BCH and nBCH • Progress reports to UNEP; • Mid-term evaluation • End-of-project evaluation	- Lack of systems for handling of applications for GMOs; - Risk assessment system for GMOs unavailable in Viet Nam; - Decision-making on GMOs done on an ad-hoc basis; - Lack of capacity in country for safe use of biotechnology.	- Establish and make operational an administrative system for handling GMO applications; - Set up an operational system for risk assessment and management; - Set up an operational system for decision-making on GMOs; - Capacity building programmes for scientific community on the safe development of biotechnology.
OUTPUT C1				

Annex 1: Logframe for Viet Nam NBF implementation project

	- Clear definition of Roles and Responsibilities for functions related to GMO applications; - Clear definition of Roles and Responsibilities for ERP, accidental release, illegal movement;	published on BCH; ▪ Responsibilities for ERP, accidental release and illegal movement published in official gazette ▪ Progress reports to UNEP; ▪ Mid-term evaluation	applications.	applications and procedures; - Clear definition of roles and responsibilities.
Proposed activities Strengthening capacity of different National Competent Authorities (NCAs) and focal points for carrying out administrative tasks. This will include: Capacity needs assessment for NCAs; Training programme for NCAs on administrative tasks as identified by the assessment. This will include workshops, seminars, study tours, on-the-job training, etc; Provide facilities for carrying out administrative tasks, including: Office equipment; Computers; Establishment of database; Information retrieval systems; Preparation of manuals and other documents setting out procedures for receipt and handling of applications; Development of guidelines for handling of: Emergency responses; Accidental releases; Illegal movement of GMOs; Transit; Contained use; AIA and FFP; Handling and transport; Packaging; Labelling; Confidential information. Identification of responsibilities of different NCAs for: Emergency responses; Accidental release; Illegal movement of GMOs; Transit; Contained use; AIA and FFP; Handling and transport; Packaging; Labelling; Identification of GMOs;				
OUTPUT C2				
A fully functional system for risk assessment	o Risk assessment criteria for GMOs in Viet Nam prepared and made available to stakeholders; o Risk assessment and management guidelines prepared and made available to all stakeholders; o National roster of risk assessment experts prepared and made available to all NCAs; o Numbers of risk assessments carried out by national reference laboratory according to international standards;	▪ RA criteria published on BCH and n BCH ▪ RA guidelines published on BCH and nBCH ▪ Annual reports of NCAs on risk assessments carried out ▪ Risk assessments reports published on BCH; ▪ National roster of experts published on BCH and nBCH ▪ Progress reports to UNEP; ▪ Mid-term evaluation	- Lack of knowledge about impacts of GMOs on biodiversity; - Lack of capacity for risk assessment and management in Viet Nam; - Lack of facilities for risk assessment and management; - Lack of facilities for contained use and field trials.	- Capacity building activities on risk assessment and management for relevant staff; - Studies on potential impacts of GMOs on biodiversity and human health in Viet Nam; - Strengthen reference laboratory for carrying out risk assessment and management; - Provision of adequate facilities for contained use and field trials.

Annex 1: Logframe for Viet Nam NBF implementation project

Proposed activities Based on NAPB Programme 3, Activity 5, carry out study on research and use of GMOs and their products in Viet Nam to identify lessons and best practices; Based on NAPB Programme 3, Activity 2, carry out research to identify and establish risk assessment criteria for Vietnamese conditions; As set out in Programme 3, Action 2 of NAPB, develop guidelines on risk assessment and management (using international experts and inter. Experts) based on: Study of existing risk assessment techniques in Viet Nam and other countries; Collection and study of relevant documents of concerned ministries and agencies; Specific techniques and procedures for risk assessment within the scope of different NCAs. Strengthening capacity of different NCAs for risk assessment Assessment of existing capacity for risk assessment Capacity needs assessment Training programme for NCAs on risk assessment as identified by the assessment (workshop, study tours) Identification of risk assessment experts for all NCAs; As set out in NAPB Programme 3, Action 4, strengthen capacity of the 1 key laboratories for carrying out risk assessment based on: Conducting survey and evaluation of technical capacity of these key laboratories in risk assessment posed by GMOs and GM products; Preparing a capacity building plan for 1 selected laboratory to meet management requirements; Strengthening professional expertise for risk assessment in the 1 selected laboratory. Assessment of existing facilities for risk assessment in the 1 key laboratory; Providing equipment and facilities for risk assessment as needed for the 1 selected laboratories; Assessment of existing contained use and field trial facilities for risk assessment for GMOs; Strengthen existing contained use and field trial facilities for risk assessment based on gaps and needs identified by assessment.				
OUTPUT C3 A fully functional system for decision-making.	o Percentage of decisions on GMO applications that comply with established national and international procedures; o Clearly defined roles and responsibilities for NCAs for decision making on GMOs made available to all stakeholders; Clear guidelines for decision	▪ Annual reports of NCAs on GMO applications ▪ NCAs responsibilities for decision making published in official gazette and on BCH; ▪ Decision making guidelines published in official gazette and nBCH. ▪ Reports of GMO decisions	- Lack of capacity for decision-making on GMOs; - Poor understanding of international requirements amongst decision-makers; - Lack of clear guidelines for decision-making on GMOs; - Lack of public participation in decision-making;	- Training for NCAs on decision-making, including international obligations; - Preparation of guidelines for decision-making on GMOs; - Studies on socio-economic impacts of GMOs and preparation of appropriate guidelines;

Annex 1: Logframe for Viet Nam NBF implementation project

Proposed activities Identify training needs for decision making in NCAs; Strengthen capacity of different NCAs for decision making through: Training of decision makers, especially in international obligations; Development of national guidelines on decision making; Establishment of mechanisms for public participation in decision making; Definition of socio-economic priorities to be taken into consideration in decision-making.				
OUTPUT C4 Capacity building for the safe development and use of biotechnology in Viet Nam	o Numbers of scientific personnel in 1 reference laboratories able to carry out risk assessment; o Percentage of scientists in key reference institutions attending training on risk assessment; Strategy for capacity building for GMO risk assessment approved by government.	▪ Results of surveys on scientific manpower published by government ▪ Capacity building Strategy for GMO risk assessment published in official gazette ▪ Roster of risk assessment experts published on BCH ▪ Progress reports to UNEP; ▪ Mid-term evaluation	- Lack of knowledge about impacts of biotechnology on biodiversity and human health amongst scientists; - Lack of sound information on biosafety in Viet Nam; - Lack of capacity for R&D on biosafety.	- Capacity building for scientists involved in biotechnology research; - Carry out studies on biosafety in Viet Nam; - Strengthen biosafety research.
Proposed activities Based on NAPB Programme 3, Action 1, evaluate R&D capacity in biotechnology and biosafety in the country and formulate a plan to strengthen this capacity. Based on NAPB Programme 3, Action 6, develop and strengthen scientific manpower in biosafety research by: Conduct survey and assessment of the current status of scientific and techni cal manpower working in biotechnology and biosafety; Evaluating training needs through survey, investigation, and review conferences; Prepare plans for strengthening human resource capacity; Identify short and long -term training solutions;				
COMPONENT: D. SYSTEMS FOR FOLLOW -UP				
OBJECTIVE D: To set in place a workable and effective national system for monitoring and enforcement	- Clear guidelines and procedures on M&E published by government and made available to stakeholders; - Percentage of monitoring requirements for GMO decisions completed as per established procedures. Clearly defined ERP roles and responsibilities for NCAs and other relevant government agencies;	▪ Guidelines and pr ocedures on M&E published in official gazette; ▪ Responsibilities for ERP published in official gazette and BCH ▪ Annual reports of NCAs ▪ Guidelines and procedures on M&E published on BCH ▪ Progress reports to UNEP; ▪ Mid-term evaluation ▪ End-of-project evaluation	- Lack of clarity about roles and responsibilities for monitoring and enforcement; - Lack of capacity for monitoring and enforcement; - Lack of a system for GMO emergency responses.	- Work with relevant agencies to define roles, responsibilities and procedures for monitoring and enforcement; - Training for NCAs on monitoring and enforcement; - Allocation of roles and responsibilities for emergency response procedures; - Training for NCAs in ERP; - Preparation of manuals and procedures for ERP

Annex 1: Logframe for Viet Nam NBF implementation project

OUTPUT D1 Well-defined roles and responsibilities of NCAs for monitoring and enforcement established.	Clear guidelines and procedures on M&E published by government and made available to stakeholders; Clearly defined roles and responsibilities for NCAs and relevant government agencies for monitoring and enforcement; Clearly defined roles and responsibilities for NCAs for enforcement of decisions on GMO applications;	▪ Responsibilities of NCAs for M&E published in official gazette and BCH ▪ Guidelines and procedures on M&E published in official gazette and on BCH ▪ Progress reports to UNEP; ▪ Mid-term evaluation	- Unclear roles and responsibilities of different agencies for monitoring and enforcement; - Lack of capacity for monitoring and enforcement amongst NCAs; - Lack of guidelines and procedures for monitoring and enforcement.	- Define roles and responsibilities in consultation with government agencies; - Training for staff of NCAs in monitoring and enforcement; - Preparation of guidelines and procedures for monitoring and enforcement.
Proposed activities Finalise survey of existing roles and responsibilities of NCAs and MONRE for monitoring; Based on results, clearly identify roles and responsibilities of NCAs and MONRE for monitoring in the biosafety decree and in sectoral regulations; Identify training needs of NCAs and MONRE for monitoring; Provide capacity building for monitoring for NCAs and MONRE through: Training workshops on monitoring; On-the-job training for relevant personnel; Study tours for relevant personnel. Provide guidelines, procedures and manuals for monitoring.				
OUTPUT D2 To strengthen national capacity for enforcement.	▪ Percentage of staff with monitoring and enforcement responsibilities in NCAs and MONRE trained; ▪ Percentage of staff in enforcement agencies completing legal training; ▪ Percentage of staff in enforcement agencies completing training in identifying potential illegal imports of GMOs; ▪ Percentage of GMO releases that comply with conditions of decisions	▪ Annual reports of NCAs ▪ Reports on GMO applications publish ed on BCH ▪ Regular Progress reports to UNEP; ▪ Mid-term evaluation	- Lack of capacity for enforcement; - Lack of clear guidelines for enforcement; - Poor definition of roles and responsibilities for enforcement; - Poor enforcement of penalties for breaches of procedures.	- Preparation of relevant raining materials and procedures for enforcement; - Clearer definition of roles and responsibilities of NCAs for enforcement; - Training for staff involved in enforcement. -
Proposed activities Carry out a survey of existing systems for enforcement of rules and regulations to identify gaps and needs; Based on results of surveys: Develop appropriate regulations, guidelines, and procedures for enforcement; Provide legal training for relevant personnel in responsible agencies in enforcement (NCAs and MONRE). Provide training in identifying illegal GMO imports for border control agencies, including customs and quarantine, as well as NCAs.				

Annex 1: Logframe for Viet Nam NBF implementation project

	agencies; Percentage of staff in relevant agencies trained in handling emergencies to do with GMOs;	▪ Progress reports to UNEP; ▪ Mid-term evaluation	procedures for enforcement; - Lack of capacity for ERP; - Poor facilities for ERP.	- Prepare guidelines and procedures for ERP in consultation with NCAs; - Training in ERP for staff in all NCAs.
Proposed activities Assign responsibilities to appropriate authorities and focal points for ERP in consultation with NCAs; Develop guidelines, rules and regulations for ERP; Define procedures for emergency responses; Provide training in ERP for both decision makers and on-the-ground personnel in ERP; Ensure adequate provision and maintenance of equipment and facilities necessary for dealing with emergencies.				
COMPONENT: E. PUBLIC AWARENESS AND PARTICIPATION				
OBJECTIVE E: To establish a workable and effective national system for public awareness, education and participation in decision making for GMOs	Percentage of public showing awareness of biosafety in surveys of public opinion; Percentage of applications receiving submissions or inputs from public; Percentage of farmers showing awareness of biosafety and dangers of illegal imports of GMOs in surveys of farmers Numbers of people participating in public meetings and debates on biosafety;	▪ Annual reports of NCAs ▪ Reports on GMO applications published on BCH ▪ Progress reports to UNEP; ▪ Mid-term evaluation ▪ End-of-project evaluation	- Poor access to biosafety information for stakeholders; - Lack of awareness of biosafety amongst stakeholders; - Lack of effective mechanisms for public participation in decision-making on GMOs.	- Establish and make operational a system for information on biosafety and decision-making on GMOs; - Awareness raising on biosafety issues; - Educational programmes on biosafety for all stakeholders; - Establish a system for public participation in decision-making on GMOs.
OUTPUT E1 A system for access to, and sharing of information, that is up and running.	Training materials on information access and sharing made available to all stakeholders Percentage of stakeholders with access to information on GMOs; Number of times that Vietnamese biosafety website is accessed Percentage of GMO applications receiving submissions or inputs from public;	▪ Training materials published and disseminated ▪ Annual reports of NCAs ▪ Records of nBCH and biosafety website ▪ Progress reports to UNEP; ▪ Mid-term evaluation	- Information systems for biosafety not available to all stakeholders; - Lack of knowledge amongst stakeholders about how to access biosafety information; - NCA staff lack capacity for dissemination of information; - Training and publicity materials not available for biosafety.	- Establish website and nBCH on biosafety; - Prepare materials (including manuals and procedures) for biosafety information sharing; - Training for relevant staff in NCAs on provision of information to stakeholders'.
Proposed activities ▪ Development of training materials, including manuals, procedures and other documentation for information sharing;				

Annex 1: Logframe for Viet Nam NBF implementation project

OUTPUT E2				
A strengthened system for public awareness on the safe use of GMOs.	Numbers of campaigns for raising public awareness on biosafety; Numbers of outreach publications on biosafety published and disseminated; Numbers of people participating in public meetings and debates on biosafety; Percentage of public showing awareness of biosafety in surveys of public opinion	▪ Survey reports; ▪ Annual reports of NCAs ▪ Records on nBCH and BCH ▪ Progress reports to UNEP; ▪ Mid-term evaluation	- Lack of capacity in NCAs on education and awareness; - Lack of awareness amongst border control agencies on biosafety; - Lack of suitable materials for education and awareness; - Awareness raising activities not targeted to specific groups.	- Training for NCA staff on education and awareness; - Preparation and dissemination of education and awareness materials on biosafety tailored to needs of specific target groups; - Training for borer control staff on biosafety.
Proposed activities				
Training for relevant staff of NCAs and other government agencies in awareness raising activities; Training in importance of biosafety for agricultural extension workers and border control staff; Production and dissemination of awareness raising materials for general public and for specific target groups such as farmers and consumers; Awareness seminars, workshops, debates and meetings for specific target groups, such as farmers, minority peoples, and consumers, on importance of biosafety; Prepare and disseminate documentary films and TV serials on biotechnological issues (namely biotechnology's achievements, prospects, potential environmental and social impacts and challenges);				
OUTPUT E3				
Strengthened system public participation in decision-making on GMOs.	Numbers of NCA decision making bodies making specific provision for public representation on their decision making body; Number of people making submissions on applications for GMO release into the environment; Numbers of people attending training workshops; % of staff dealing with GMOs in NCAs trained in public participation;	▪ Annual reports of NCAs ▪ Reports on GMO applications and decisions published on BCH ▪ Progress reports to UNEP; ▪ Mid-term evaluation	- GMO decision-making system does not provide for public participation; - Public lack access to information on GMO applications.	- Ensure that draft regulations provide for public participation in decision-making; - Consult with all stakeholders in finalising biosafety regulations; - Ensure public access to non-confidential information.
Proposed activities				
▪ Identify and institutionalize entry points for public participation in decision-making on GMOs; ▪ Develop mechanisms for public involvement in biosafety management; ▪ Training for NCA staff on facilitating public participation into				

ANNEX 2: ACTIVITY BASED BUDGET

Activity code	PROJECT ACTIVITIES	GEF	Cofinancing	Total
1	**Integration of biosafety into national sectoral action plans and strategies**	**53000**	**16000**	**69000**
1.1	**Government recognises the importance of biosafety for sustainable development by approving the National Action Plan on Biosafety to 2010.**	**11000**	**3000**	**14000**
1.1.1	Provide briefing for PM & cabinet on biosafety as a sustainable development issue;	0	1000	1000
1.1.2	Prepare brief on costs and benefits of NAPB to identify synergies between development of biotechnology and sustainable use of biodiversity resources;	2000		2000
1.1.3	Consultations with relevant government agencies to review NAPB to ensure its compatibility with sectoral plans and strategies;	4000	1000	5000
1.1.4	Peer review of NAPB to ensure its consistency with Cartagena Protocol;	2000		2000
1.1.5	Based on results of consultations and peer review, revise NAPB as necessary.	3000	1000	4000
1.2	**Biosafety action plan integrated into national sectoral plans and strategies for Biodiversity, environmental protection, Biotechnology, Agriculture, Fisheries, Trade, and Health.**	**42000**	**13000**	**55000**
1.2.1	Carry out a series of awareness seminars on NAPB for policy makers and planners from sectoral government agencies;	6000	3000	9000
1.2.2	Contract national consultants to carry out study of how biosafety fits into sectoral plans, based on an analysis of sectoral plans and NAPB;	10000	5000	15000
1.2.3	Brief science and technology policy committees on the contribution of NAPB to sectoral plans and strategies.	2000	1000	3000
1.2.4	Awareness seminars on Cartagena Protocol, synergies between biosafety and biotechnology	24000	4000	28000
2	**Proposed Activities for Regulatory regime**	**109000**	**28000**	**137000**
2.1	**A regulatory regime in place for management of GMOs.**	**12000**	**13000**	**25000**
2.1.1	Based On NAPB, prepare a draft of biosafety provisions in the law on biodiversity;	6000	0	6000
2.1.2	Formulate government decree on management of GMOs as set out in NAPB;	1000	3000	4000
2.1.3	Formulate regulations for EIA for GMOs and their products as set out in the NAPB (programme 1, action 4);	5000	10000	15000
2.2	**Biosafety regulations formulated for GMO management in different sectors.**	**63000**	**13000**	**76000**
2.2.1	Study of examples of sectoral regulations/guidelines/experiences from other countries;	6000	3000	9000
2.2.1	Work with relevant government agencies to formulate draft sectoral regulations for management of biosafety	30000	10000	40000
2.2.3	Consult with all relevant government agencies and stakeholders on proposed sectoral regulations for GMOs, using international and/or regional experts for peer review;	15000	0	15000

2.2.4	Finalise and promulgate sectoral regulations for GMOs based on results of consultations.	12000	0	12000
2.3	**Biosafety regulations formulated and promulgated for trade in GMOs and their products.**	**34000**	**2000**	**36000**
2.3.1	Study of examples of experiences from other countries on regulation of in trading GMOs and their products;	5000	0	5000
2.3.2	Work with relevant government agencies to formulate draft regulations for import and export of GMOs and their products to include specific provisions for import and export; Advanced notification; Safety monitoring and management in import-export process; Transit; Transport; Labelling requirements for commodities containing GMOs and their products; Investment activities; Damage compensation; and Dispute settlement procedures.	8000	0	8000
2.3.3	Consult with all relevant government agencies and stakeholders on proposed import and export regulations for GMOs;	2000	0	2000
2.3.4	Finalise and promulgate import and export regulations for GMOs based on results of consultations and expert advice. 5000	5000	0	5000
2.3.5	Provide training for relevant personnel on international obligations and drafting of appropriate regulations using international and/or regional experts	14000	2000	16000
3	**Proposed Activities for Handling requests for permits**	**336000**	**329000**	**665000**
3.1	**A fully functional administrative system for handling requests for GMOsStrengthening capacity of different National Competent Authorities (NCAs) and focal points for carrying out administrative tasks. This will include:**	**95000**	**65000**	**160000**
3.1.1	Capacity needs assessment for NCAs;	13000	13000	26000
3.1.2	Training programme for NCAs on administrative tasks as identified by the assessment. This will include workshops, seminars, study tours, on-the-job training, etc;	25000	5000	30000
3.1.3	Provide facilities for carrying out administrative tasks, including office equipment;	5000	25000	30000
3.1.4	Preparation of manuals and other documents setting out procedures for receipt and handling of applications;	20000	0	20000
3.1.5	Development of guidelines for handling of: Emergency responses; Accidental releases; Illegal movement of GMOs; Transit; Contained use; AIA and FFP; Handling and transport; Packaging; Labelling; Confidential information.	30000	20000	50000
3.1.6	Identification of responsibilities of different NCAs for: Emergency responses; Accidental release; Illegal movement of GMOs; Transit; Contained use; AIA and FFP; Handling and transport; Packaging; Labelling; Identification of GMOs;	2000	2000	4000
3.2	**A fully functional system for risk assessment.**	**160000**	**211000**	**371000**
3.2.1	Based on NAPB Programme 3, Activity 5, carry out study on research and use of GMOs and their products in Viet Nam to identify lessons and best practices;	7000	5000	12000

3.2.2	Based on NAPB Programme 3, Activity 2, carry out research to identify and establish risk assessment criteria for Vietnamese conditions;	5000	1000	6000
3.2.3	As set out in Programme 3, Action 2 of NAPB, develop guidelines on risk assessment and	20000	15000	35000
3.2.4	Strengthening capacity of different NCAs for risk assessment			0
3.2.4.a	*Workshoop on Risk assessment and management*	*21000*	*0*	21000
3.2.4.b	*Study tour on Risk assessment and management*	*20000*	*0*	20000
3.2.5	Identification and development of risk assessment expert network for all NCAs;	2000	0	2000
3.2.6	As set out in NAPB Programme 3, Action 4, strengthen capacity of the 1 key laboratories for carrying out risk assessment	50000	150000	200000
3.2.7	Assessment of existing contained use and field trial facilities for risk assessment for GMOs;	15000	10000	25000
3.2.8	Strengthen existing contained use and field trial facilities for risk assessment based on gaps and needs identified by assessment.	20000	30000	50000
3.3	**A fully functional system for decision making**	**61000**	**13000**	**74000**
3.3.1	Strengthen capacity of different NCAs for decision making on biosafety	20000	10000	30000
3.3.2	Workshop on handling applications and decision making on GMOs	21000	3000	24000
3.3.3	Study tour on Handling applications and decision making on GMOs	20000	0	20000
3.4	**Capacity building for the safe development and use of biotechnology in Viet Nam.**	**20000**	**40000**	**60000**
3.4.1	Based on NAPB Programme 3, Action 1, evaluate R&D capacity in biotechnology and biosafety in the country and formulate a plan to strengthen this capacity.	10000	10000	20000
3.4.2	Based on NAPB Programme 3, Action 6, develop and strengthen scientific manpower in biosafety research	10000	30000	40000
4	**Proposed Activities System for follow-up (Monitoring of environmental effects, inspections and enforcement)**	**136000**	**38000**	**174000**
4.1	**Well-defined roles and responsibilities of NCAs for monitoring and enforcement (M&E) established.**	**20000**	**10000**	**30000**
4.1.1	Finalise survey of existing roles and responsibilities of NCAs and MONRE for monitoring;	5000	5000	10000
4.1.2	Based on results, clearly identify roles and responsibilities of NCAs and MONRE for monitoring in the biosafety decree and in sectoral regulations;	5000	5000	10000
4.1.3	Identify training needs of NCAs and MONRE for monitoring;	5000	0	5000
4.1.4	Provide guidelines, procedures and manuals for monitoring.	5000	0	5000
4.2	**To strengthen national capacity for enforcement.**	**96000**	**18000**	**114000**
4.2.1	Carry out a survey of existing systems for enforcement of rules and regulations to identify gaps and needs;	10000	5000	15000
4.2.2	Develop appropriate regulations, guidelines, and procedures for enforcement;	10000	5000	15000
4.2.3	Workshop on Enforcement of GMO regulations	21000	3000	24000

4.2.3	Training on Monitoring, QA for detection of GMOs	30000	3000	33000
4.2.4	a. Study tour on Identification and detection of GMOs;b. Quantification and determination of the content of GMOs in non-GMOs and their products;c. Quality Assurance in the analysis on GMOs	25000	2000	27000
4.3	**To establish and make operational emergency response procedures (ERP).**	**20000**	**10000**	**30000**
4.3.1	Develop guidelines, rules and regulations for ERP;	10000	5000	15000
4.3.2	Define procedures for emergency responses;	10000	5000	15000
5	**Proposed Activities for Public information, participation, awareness**	**135000**	**59000**	**194000**
5.1	**A system for access to, and sharing of information, that is up and running.**	**40000**	**20000**	**60000**
5.1.1	Development of training materials, including manuals, procedures and other documentation for information sharing,	20000	10000	30000
5.1.2	Development and dissemination of outreach materials on access to information (newsletter, etc);	20000	10000	30000
5.2	**A strengthened system for public awareness and education on the safe use of GMOs..**	**75000**	**29000**	**104000**
5.2.1	Identify relevant government agencies for managing public and specific target group awareness programmes;	0	0	0
5.2.2	Training for relevant staff of NCAs and other government agencies in awareness raising activities;	10000	5000	15000
5.2.3	Production and dissemination of awareness raising materials for general public and for specific target groups such as farmers and consumers;	15000	5000	20000
5.2.4	Awareness seminars, workshops, debates and meetings for specific target groups, such as farmers, minority peoples, and consumers, on importance of biosafety;	20000	4000	24000
5.2.5	Prepare and disseminate documentary films and TV serials on biotechnological issues (namely biotechnology's achievements, prospects, potential environmental and social impacts and challenges);	30000	15000	45000
5.3	**Strengthened system public participation in decision making on GMOs.**	**20000**	**10000**	**30000**
5.3.1	Develop mechanism for public involvement in biosafety management	2000	2000	4000
5.3.2	Identify and institutionalize entry points for public participation in decision-making on GMO	2000	2000	4000
5.3.3	Training for NCA staff on facilitating public participation into decision making on GMOs;	6000	3000	9000
5.3.4	4) Training workshops for stakeholders on how to contribute to decision making on GMOs.	10000	3000	13000
6	**Project Coordination**	**120800**	**84000**	**204800**
6.1	NPD	14400	24000	38400
6.2	NPC	38400	0	38400
6.3	Accountant	24000	0	24000

6.4	Secreatary	24000	0	24000
6.5	NCC travel and perdiem	20000	60000	80000
7	**Technical suport**	**70000**	**0**	**70000**
8	**Equipment and operating costs:**	**38000**	**83000**	**121000**
8.1	Project office equipment and maiternance	8000	13000	21000
8.2	Office supplier	10000	60000	70000
8.3	Communication cost	10000	10000	20000
8.4	Audit	5000	0	5000
8.5	Contingency	5000	0	5000
	Total	**997800**	**637000**	**1634800**

Annex 3: Implementation plan

	Activities	Responsi	Year 1				Year 2				Year 3				Year 4			
I	**Preliminary Activities including Institutional Arrangement**																	
	Establishment of the PCC and a working group responsible for its administrative work.		■															
	Nomination of a full time NPC and project staffs		■															
	Communicate to UNEP name and contact details of NPC, project staffs and composition of the PCC		■															
	Equip project office		■															
	Inception Workshop		■															
	Develop project annual Plan		■															
II	**Project Activities**		■															
A.	**Develop Biosafety Policy**																	
A1	**Government recognises the importance of biosafety for sustainable development by approving the National Action Plan on Biosafety to 2010.**																	
	Provide briefing for PM & cabinet on biosafety as a sustainable development issue;			■														
	Prepare brief on costs and benefits of NAPB to identify synergies between development of biotechnology and sustainable use of biodiversity resources;				■													
	Consultations with relevant government agencies to review NAPB to ensure its compatibility with sectoral plans and					■												
	Peer review of NAPB to ensure its consistency with Cartagena Protocol;					■												
	Based on results of consultations and peer review, revise NAPB as necessary.																	
A2	**Biosafety action plan integrated into national sectoral plans and strategies for Biodiversity, environmental protection, Biotechnology, Agriculture, Fisheries, Trade, and Health.**					■	■	■	■	■								
	Carry out a series of awareness seminars on NAPB for policy makers and planners from sectoral government agencies;			■	■	■												

	Contract national consultants to carry out study of how biosafety fits into sectoral plans, based on an analysis of sectoral plans and																		
	Work with relevant ministries and agencies to review sectoral plans to identify how NAPB can contribute to sectoral priorities;																		
	Brief science and technology policy committees on the contribution of NAPB to sectoral plans and strategies.																		
A1 & A2	*Awareness seminars on Cartagena Protocol, synergies between biosafety and biotechnology*																		
B	**Proposed Activities for Regulatory regime**																		
B1	**A regulatory regime in place for management of GMOs.**																		
	Training for relevant personnel in international obligations and requirements of Cartagena Protocol, other MEAs, trade agreements, etc. (using international expert)																		
	Based On NAPB, prepare a draft of biosafety provisions in the law on biodiversity;																		
	Formulate government decree on management of GMOs as set out in NAPB;																		
	Formulate regulations for EIA for GMOs and their products as set out in the NAPB (programme 1, action 4);																		
	Draft ordinance on biosafety:																		
B2	**Biosafety regulations formulated for GMO management in different sectors.**																		
	Study of examples of sectoral regulations/guidelines/experiences from other countries;																		
	Work with relevant government agencies to formulate draft sectoral regulations for management of biosafety																		
	Consult with all relevant government agencies and stakeholders on proposed sectoral regulations for GMOs, using international and/or regional experts for peer review;																		
	Finalise and promulgate sectoral regulations for GMOs based on results of consultations.																		
B3	**Biosafety regulations formulated and promulgated for trade in GMOs and their products.**																		
	Study of examples of experiences from other countries on regulation of in trading GMOs and their products;																		

	Work with relevant government agencies to formulate draft regulations for import and export of GMOs and their products to include specific provisions for import and export; Advanced notification; Safety monitoring and management in import-export process; Transit; Transport; Labelling requirements for commodities containing GMOs and their products; Investment activities; Damage compensation; and Dispute settlement procedures.																		
	Consult with all relevant government agencies and stakeholders on proposed import and export regulations for GMOs;																		
	Finalise and promulgate import and export regulations for GMOs based on results of consultations and expert advice. 5000																		
B1 to B3	*Provide training for relevant personnel on international obligations and drafting of appropriate regulations using international and/or regional*																		
C.	**Proposed Activities for Handling requests for permits**																		
C1	**A fully functional administrative system for handling requests for GMOsStrengthening capacity of different National Competent Authorities (NCAs) and focal points for carrying out administrative tasks. This will include:**																		
	Capacity needs assessment for NCAs;																		
	Training programme for NCAs on administrative tasks as identified by the assessment. This will include workshops, seminars, study tours, on-the-job training, etc;																		
	Provide facilities for carrying out administrative tasks, including: Office equipment; Computers; Establishment of database;																		
	Access to BCH.																		
	Preparation of manuals and other documents setting out procedures for receipt and handling of applications;																		
	Development of guidelines for handling of: Emergency responses; Accidental releases; Illegal movement of GMOs; Transit; Contained use; AIA and FFP; Handling and transport; Packaging; Labelling; Confidential information.																		
	Identification of responsibilities of different NCAs for: Emergency responses; Accidental release; Illegal movement of GMOs; Transit; Contained use; AIA and FFP; Handling and transport; Packaging; Labelling; Identification of GMOs;																		

C2	**A fully functional system for risk assessment.**																	
	Carry out study on research and use of GMOs and their products in Viet Nam to identify lessons and best practices;																	
	Carry out research to identify and establish risk assessment criteria for Vietnamese conditions;																	
	Strengthening capacity of different NCAs for risk assessment																	
	Identification of risk assessment experts for all NCAs;																	
	As set out in NAPB Programme 3, Action 4, strengthen capacity of the 1 key laboratory for carrying out risk assessment																	
	Assessment of existing contained use and field trial facilities for risk assessment for GMOs;																	
	Strengthen existing contained use and field trial facilities for risk assessment based on gaps and needs identified by assessment.																	
	Workshoop on Risk assessment and management																	
	Study tour on Risk assessment and management																	
C3	**A fully functional system for decision making**																	
	Identify training needs for decision making in NCAs;																	
	Strengthen capacity of different NCAs for decision making through:30000																	
C1 & C3	Workshop on handling applications and decision making on GMOs																	
C1 and C3	Study tour on Handling applications and decision making on GMOs																	
C4	**Capacity building for the safe development and use of biotechnology in Viet Nam.**																	
	Based on NAPB Programme 3, Action 1, evaluate R&D capacity in biotechnology and biosafety in the country and formulate a plan to strengthen this capacity.																	
	Based on NAPB Programme 3, Action 6, develop and strengthen scientific manpower in biosafety research																	
D.	**Proposed Activities System for follow-up (Monitoring of environmental effects, inspections and enforcement)**																	
D1	**Well-defined roles and responsibilities of NCAs for monitoring and enforcement (M&E) established.**																	
	Finalise survey of existing roles and responsibilities of NCAs and MONRE for monitoring;																	

	Based on results, clearly identify roles and responsibilities of NCAs and MONRE for monitoring in the biosafety decree and in sectoral regulations;																	
	Identify training needs of NCAs and MONRE for monitoring;																	
	Provide capacity building for monitoring for NCAs and MONRE as following:																	
	Training workshops on monitoring;																	
	On-the-job training for relevant personnel;																	
	Study tours for relevant personnel.																	
	Provide guidelines, procedures and manuals for monitoring.																	
D2	**To strengthen national capacity for enforcement.**																	
	Carry out a survey of existing systems for enforcement of rules and regulations to identify gaps and needs;																	
	Based on results of surveys:Develop appropriate regulations, guidelines, and procedures for enforcement																	
	Workshop on Enforcement of GMO regulations																	
D1&D 2	Training on Monitoring, QA for detection of GMOs																	
D1&D 2	Study tour on: a. Identification and detection of GMOs;b. Quantification and determination of the content of GMOs in non-GMOs and their products;c. Quality Assurance in the analysis on																	
D3	**To establish and make operational emergency response procedures (ERP).**																	
	Assign responsibilities to appropriate authorities and focal points for ERP in consultation with NCAs;																	
	Develop guidelines, rules and regulations for ERP;																	
	Define procedures for emergency responses;																	
E.	**Proposed Activities for Public information, participation, awareness**																	
E1	**A system for access to, and sharing of information, that is up and running.**																	
	Training for Focal Points and relevant staff of NCAs in BCH;																	
	Development and dissemination of outreach materials on access to information (newsletter, website, etc);																	
	Establish a website on biosafety for pubic access and information exchange;																	

	Use existing tools for networking and knowledge management.																		
E2	**A strengthened system for public awareness and education on the safe use of GMOs..**																		
	Identify relevant government agencies for managing public and specific target group awareness programmes;																		
	Production and dissemination of awareness raising materials for general public and for specific target groups such as farmers and																		
	Awareness seminars, workshops, debates and meetings for specific target groups, such as farmers, minority peoples, and consumers, on importance of biosafety;																		
	Prepare and disseminate documentary films and TV serials on biotechnological issues (namely biotechnology's achievements, prospects, potential environmental and social impacts and																		
	Publish general knowledge textbooks about modern biotechnology and biosafety.																		
E3	**Strengthened system public participation in decision making on GMOs.**																		
	Inclusion of specific provision for participation by representatives of specific stakeholders in GMO regulations and																		
	Establish provisions for public consultation in administrative procedures for GMO decision making by NCAs and MONRE;																		
	Establish public groups participating in biosafety management and provide training on key issues for management of GMOs;																		
	Establish procedures for publication of relevant information on GMO application in public website and nBCH;																		
F	**Project Management**																		
D	**Monitoring and evaluation**																		

ANNEX 4

Draft Terms of Reference for:

- **National Executing Agency (NEA)**
- **National Coordinating Committee (NCC)**
- **National Project Director (NPD)**
- **National Project Coordinator (NPC)**
- **National Project Assistant(s)**

a) The **National Executing Agency (NEA),** in addition to other duties given to it by the National Government, will:

- Establish the National Co-ordinating Committee (NCC);
- Appoint a part-time National Project Director (NPD) and a full time National Project Co-ordinator (NPC), taking into account the sustainability of national biosafety activities on completion of the National Project;
- Provide the necessary scientific, technical, financial and administrative support to the work of the NCC, working in close co-operation with relevant government agencies, the scientific community and the public and private sectors.

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

- Develop a common understanding of what is needed to expedite the implementation of the National Biosafety Framework;
- Mobilise necessary expertise, as needed for the proper execution of the National Project outputs;
- Provide overall policy advice on the implementation of the National Project;
- Review and advise on the main outputs of the National Project;
- Ensure that information on the execution of the National Project as well as the National Project outputs is brought to the attention of local and national authorities for follow up;
- Assist in mobilising available data and ensure a constant information flow between all concerned parties;
- Allow for effective communication and decision-making between the National Project Coordinator and other actors;

- **National Project Director (NPD)**
- The National Project Director (NPD) will act as the Chairman of the NCC
- Approve the detailed work plan and budget produced by the NPC;
- Oversee the execution of the project;
- Ensure that the environmental policy of the Government is fully reflected in the National Project documentation;
- Prepare and oversee the development of Terms of Reference for National Project components, consultants and experts;
-
- Ensure that regular reports, financial accounts, and requests are submitted to UNEP as set out in section 6;
- Review all documentation deriving from the National Project and any other relevant documentation to ensure that these are consonant with National Government;
- Submit the final report within three months from the end of the project.

c) The **National Project Coordinator (NPC)** will carry out the following tasks

- The National Project Coordinator (NPC) will act as the secretary of the NCC

- Coordinate, manage and monitor the execution of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Organize National Coordinating Committee meetings;
- Update the detailed work plan and propose adjustments within the agreed a budget as needed and under the guidance of the NPD and NCC;
- Ensure effective communication with the relevant authorities, institutions and government departments in close collaboration with the National Coordinating Committee;
- Foster, establish and maintain links with other related national and international programmes and National Projects;
- Prepare and oversee the development of Terms of Reference for National Project components, consultants and experts;
- Organize, contract and manage the consultants and experts, and supervise their performance;
- Coordinate and oversee the preparation of the outputs of the NBF;
- Manage the National Project finance, oversee overall resource allocation and where relevant submit proposals for budget revisions to the NCC and UNEP;
- Manage the overall National Project ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Coordinate the work of all stakeholders under the guidance of the NEA, NDP and the NCC and in consultation with the UNEP Global National Project Team;
- Ensure that information is available to the NPD, NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
- Prepare and submit to UNEP and the NPD, regular progress and financial reports

c) The **Project Assistants (PA)** will carry out the following tasks

- Assist the NPC in the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Assist with the organisation of National Coordinating Committee meetings;
- Assist with preparation detailed work plan and budget under the guidance of the NPD;
- Support the NPC in maintaining effective communication with the relevant authorities, institutions and government departments;
- Inform the NPC of other related national and international programmes and National Projects;
- Assist in drafting Terms of Reference for National Project components, consultants and experts;
- Assist with the identification of the consultants and experts, and supervise their performance;
- Assist in overseeing the preparation of the outp uts of the NBF;
- Assist the National Project Finance Officer providing information as needed;
- Assist the NPC ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Assist in providing information to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
- Assist the NPC in the preparation and submission to UNEP and the NCC, of regular progress and financial reports
- Assist with the preparation of a project monitoring and evaluation plan
- Assist with identification of appropriate project indicators able to reflect progress of activities as well as impact
- Assist with capturing and incorporating recommendations from NCC meetings into project execution and monitoring and evaluation plan
- Assisting with providing information as needed to carry out any monitoring and evaluation activity as part of the UNEP's internal guidelines

Annex 5:

DECISION No. 212/2005/QD-TTg OF AUGUST 26, 2005, PROMULGATING THE REGULATION ON MANAGEMENT OF BIOLOGICAL SAFETY OF GENETICALLY MODIFIED ORGANISMS; PRODUCTS AND GOODS ORIGINATING FROM GENETICALLY MODIFIED ORGANISMS

THE PRIME MINISTER

Pursuant to the December 25, 2001 Law on Organization of the Government;

Pursuant to the December 27, 1993 Law on Environmental Protection;

At the proposal of the Minister of Natural Resources and Environment,

DECIDES:

Article 1.- To promulgate together with this Decision the Regulation on management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms.

Article 2.- The Minister of Natural Resources and Environment shall assume the prime responsibility for, and coordinate with concerned ministries, branches and localities in, guiding and organizing the implementation of the Regulation promulgated together with this Decision.

Article 3.- This Decision takes effect 15 days after its publication in "CONG BAO."

Ministers, heads of ministerial-level agencies, heads of Government-attached agencies, presidents of provincial/municipal People's Committees, and concerned organizations and individuals shall have to implement this Decision.

For the Prime Minister
Deputy Prime Minister
PHAM GIA KHIEM

REGULATION ON MANAGEMENT OF BIOLOGICAL SAFETY OF GENETICALLY MODIFIED ORGANISMS; PRODUCTS AND GOODS ORIGINATING FROM GENETICALLY MODIFIED ORGANISMS

Chapter I

GENERAL PROVISIONS

Article 1.- Scope of regulation

This Regulation provides for the state management of biological safety in scientific research, technological development and assay; production, trading and use; import, export, storage and transportation; risk evaluation and management and grant of biological safety certificates for genetically modified organisms; products, goods originating from genetically modified organisms for the purpose of protecting human health, the environment and bio-diversity.

Article 2.- Subjects of application

This Regulation applies to domestic and foreign organizations and individuals (hereinafter referred to as organizations and individuals) engaged in activities related to genetically modified organisms; and products, goods originating from genetically modified organisms in the Vietnamese territory.

Where treaties which the Socialist Republic of Vietnam has signed or acceded to contain provisions different from those of this Regulation, the provisions of such treaties shall apply.

Article 3.- Interpretation of terms

In this Regulation, the following terms shall be construed as follows:

1. Biological safety means measures to manage safety in scientific research, technological development and assay; production, trading and use; import, export, storage and transportation; risk evaluation and management and grant of biological safety certificates for genetically modified organisms; products, goods originating from genetically modified organisms.

2. Gene means a unit of heredity, a segment of genetic material of an organism determining the particular characteristics of the organism.

3. DNA (deoxyribonucleic acid) means genetic material of an organism, shaped like a double helix and composed of a lot of genes (units of heredity).

4. Gene transfer technology means the transfer of a gene of one organism to another, forcing the DNA helix of the target organism to accept the foreign gene.

5. Genetically modified organisms mean animals, plants or micro-organisms whose genetic structure has been altered by gene transfer technology.

6. Products or goods originating from genetically modified organisms mean products or goods created wholly or partly from genetically modified organisms.

7. Release of genetically modified organisms means the deliberate introduction into the environment of genetically modified organisms.

8. Risk assessment means the determination of the potential hazard and the extent of damage which has been caused or might be caused to human health, the environment and bio-diversity in activities related to genetically modified organisms, particularly the use and release of genetically modified organisms; and to products and goods originating from genetically modified organisms.

9. Risk management means the application of safety measures to prevent, deal with and overcome risks to human health, the environment and bio-diversity in activities related to genetically modified organisms, products and goods originating from genetically modified organisms.

10. Assay means activities of testing the level of biological safety of genetically modified organisms, products and goods originating from genetically modified organisms under the practical conditions of Vietnam before they are put to production, trading and use.

Chapter II

SCIENTIFIC RESEARCH, TECHNOLOGICAL DEVELOPMENT AND ASSAY

Article 4.- Scientific research, technological development

1. Scientific research, technological development concerning genetically modified organisms; products and goods originating from organisms must comply with current regulations on scientific and technological management and other relevant provisions of law.

2. Organizations and individuals may conduct scientific research, technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms only when they have all conditions regarding material foundations, equipment, technology and professional personnel suitable for scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms.

3. Organizations and individuals, when conducting scientific research, technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms, must register such activities with the Ministry of Science and Technology and ministries managing this issue.

4. Organizations and individuals conducting scientific research, technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms shall have to safely preserve genetically modified organisms and other related dangerous materials and keep them from leaking into the environment.

Article 5.- Assay

Organizations and individuals assaying genetically modified organisms; products or goods originating from genetically modified organisms must observe the following provisions:

1. Conditions for registration of assaying activities:

a/ Having adequate material and technical foundations, technology and specialized staff suitable for the assay of each kind of genetically modified organism, product or goods originating from genetically modified organisms for the efficient control and handling of risks under regulations of the concerned managing ministry;

b/ Genetically modified organisms, products and goods originating from genetically modified organisms which need to be assayed must be the outcome of the process of scientific research which has been tested and accepted by a competent state agency;

c/ Having risk monitoring and management measures in the assay process;

d/ The area where an assay takes place must be isolated from population quarters and nature conservation zones according to regulations of the concerned managing ministry.

2. A registration dossier consists of:

a/ An application for registration of assay;

b/ Written consent of the People's Committee of the province or centrally-run city where the assay is planned to be conducted;

c/ Papers proving full satisfaction of the conditions specified in Clause 1 of this Article;

d/ Other necessary relevant information as requested by the registry.

3. Order and procedures:

a/ Dossiers of registration of assay shall be sent to the concerned ministry;

b/ Within 60 days after receipt of complete and valid dossiers, the concerned ministry shall have to evaluate the dossiers and issue decisions to permit the assay in cases where all conditions are met; if refusing to permit an assay, the dossier-receiving ministry must issue a written reply, clearly stating the reason therefor.

4. When permitting an organization or individual to conduct an assay, the concerned managing ministry shall have to report it to the Ministry of Natural Resources and Environment, the focal point of the Government.

Chapter III

PRODUCTION, TRADING AND USE

Article 6.- Conditions on production and trading

1. Organizations or individuals may produce, trade in or put to use genetically modified organisms; products and goods originating from genetically modified organisms when they fully meet the following conditions:

a/ Having biological safety certificates for genetically modified organisms; products or goods originating from genetically modified organisms;

b/ Genetically modified organisms, products or goods originating from genetically modified organisms are on the list of those permitted for production, trading and use under regulations of the concerned ministries.

2. Organizations or individuals that produce, trade in or put to use genetically modified organisms, products or goods originating from genetically modified organisms must have relevant production or business registration certificates.

Article 7.- Labeling

Organizations and individuals that have products or goods being genetically modified organisms, products or goods originating from genetically modified organisms circulated and traded on the market must comply with current provisions of law on goods labeling and print on their packings the following words: "Products using gene transfer technology" for consideration and selection by consumers.

Article 8.- Monitoring, supervision and reporting

Organizations and individuals that produce and/or trade in genetically modified organisms, products or goods originating from genetically modified organisms must regularly monitor and supervise their level of safety for human health, the environment and biodiversity; when a risk occurs, they must immediately report it to the Ministry of Natural Resources and Environment and the concerned managing ministries.

Chapter IV

IMPORT, EXPORT, STORAGE AND TRANSPORTATION

Article 9.- Conditions on import of genetically modified organisms

1. Genetically modified organisms imported into Vietnam for research purposes must satisfy the following conditions:

a/ Having been permitted by the exporting country for use for the same purpose in its territory;

b/ Having effective risk management measures.

2. Genetically modified organisms imported into Vietnam for assay, production, trading or use purposes must satisfy the following conditions:

a/ Having been permitted by the exporting country for use for the same purpose in its territory;

b/ Having gone through risk assessment in the practical conditions of the exporting country; in case of import for production, trading or use purposes, genetically modified organisms must have also undergone risk assessment in the practical conditions of Vietnam;

c/ The exporting country has established an effective safety management mechanism for such genetically modified organisms.

Article 10.- Conditions on import of products and goods originating from genetically modified organisms

1. Products and goods originating from genetically modified organisms imported into Vietnam for research purposes must comply with the provisions of Clause 1, Article 9 of this Regulation.

2. Products and goods originating from genetically modified organisms for assay, production, trading or use purposes must satisfy the following conditions:

a/ Having been permitted by the exporting country for use for the same purpose in its territory;

b/ Having gone through risk assessment in the practical conditions of the exporting country;

c/ The exporting country has established an effective safety management mechanism for such products or goods originating from genetically modified organisms;

d/ Where the exporting country and Vietnam have a document on mutual recognition of products and goods originating from genetically modified organisms, the conditions on the import thereof shall comply with such document.

Article 11.- Import procedures

The import of genetically modified organisms, products or goods originating from genetically modified organisms must comply with current provisions of law on import. Besides, the following procedures must be carried out:

1. Importing organizations or individuals shall send written applications for permission for import, which are enclosed with necessary information specified in Appendix I to this Regulation (not printed herein) to the concerned managing ministries for consideration.

2. The concerned managing ministries shall examine dossiers and issue written decisions regarding safety in the import of genetically modified organisms, products or goods originating from genetically modified organisms and notify the Ministry of Natural Resources and Environment for knowledge and joint monitoring.

Article 12.- Export

The export of genetically modified organisms, products or goods originating from genetically modified organisms to abroad must comply with legal provisions on export of Vietnam and the exporting country as well as treaties which the Socialist Republic of Vietnam has signed or acceded to.

Article 13.- Storage and transportation

1. In the course of storage or transportation, genetically modified organisms, products or goods originating from genetically modified organisms must be carefully packaged, applied with leak-preventing safety measures, and labeled in accordance with current provisions of Vietnamese law and international practices.

2. In case of domestic transportation, before commencing transportation of genetically modified organisms, products or goods originating from genetically modified organisms, their owners must send written notices thereon to the concerned managing ministries, clearly stating information printed on their labels, place of manufacture, warehouse, preservation measures, means of transport, place of departure, place of destination, measures to ensure safety in the course of transportation and the specific duration of transportation.

3. In case of transit of genetically modified organisms, products or goods originating from genetically modified organisms through the territory of Vietnam with discharge thereof at port, their owners must send documents containing necessary information, made according to a set form, to the concerned managing ministries for consideration. The General Department of Customs shall carry out relevant procedures only after having received opinions regarding biological safety of the above-said products or goods from the concerned managing ministries.

4. In case of transit of genetically modified organisms, products or goods originating from genetically modified organisms through the territory of Vietnam without discharge thereof at port, their owners must send written notices on measures to ensure safety in the course of transit to the concerned managing ministries for consideration and decision. The General Department of Customs shall carry out relevant procedures only after having received opinions regarding this issue from the concerned managing ministries.

Chapter V

RISK ASSESSMENT, RISK MANAGEMENT AND GRANT OF BIOLOGICAL SAFETY CERTIFICATES

Article 14.- Risk assessment

1. Organizations and individuals, before releasing genetically modified organisms, products or goods originating from genetically modified organisms into the environment or producing, trading in or using them, must conduct risk assessment in order to determine the possibility of risks which may be caused by such genetically modified organisms, products or goods to human health, the environment and bio-diversity according to regulations of the ministries responsible for this issue.

2. Risk assessment must be conducted using the methods and techniques of risk assessment already recognized and based on information specified in Appendix II to this Regulation (not printed herein) and other relevant scientific evidence.

3. Risk assessment must be conducted under the supervision of one or more specialized scientific agencies whose supervisory capabilities have been recognized by the concerned managing ministries.

4. The results of risk assessment shall be recorded in risk assessment reports made by risk-assessing organizations or individuals according to a set form.

Article 15.- Risk management

1. In scientific research, technological development, assay; production, trading and use; import, export, storage, and transportation of genetically modified organisms, products and goods originating from genetically modified organisms, risk prevention, handling and remedy measures must be taken.

2. Organizations and individuals conducting scientific research, technological development, assay of genetically modified organisms, products and goods originating from genetically modified organisms must assist concerned organizations and individuals in applying measures to prevent, handle and overcome risks in the process of assay and application of genetically modified organisms, products or goods originating from genetically modified organisms which they have created.

3. Organizations and individuals exporting, importing or using genetically modified organisms, products and goods originating from genetically modified organisms shall have to apply appropriate control measures to prevent, detect in time and handle risks so as to overcome their consequences; when a risk occurs in their activities, they must promptly report it to the Ministry of Natural Resources and Environment and concerned managing ministries for handling.

Article 16.- Grant of biological safety certificates

1. After having undergone assay and risk assessment, if meeting all conditions on biological safety according to the provisions of Clause 2 of this Article, genetically modified organisms, products and goods originating from genetically modified organisms shall be considered, granted biological safety certificates and included by the concerned managing ministries on the lists of those permitted for production, trading and use. The managing ministries which have granted biological safety certificates for genetically modified organisms, products or goods originating from genetically modified organisms shall be entitled to withdraw such certificates.

2. Genetically modified organisms, products and goods originating from genetically modified organisms shall be recognized to have ensured biological safety if they fully meet the following conditions:

a/ Not causing any toxicity or allergy to human health;

b/ Not causing adverse impacts on the environment and biodiversity.

3. The managing ministries shall have to report to the Ministry of Natural Resources and Environment, the focal point of the Government, on the grant of biological safety certificates for genetically modified organisms, products of goods originating from genetically modified organisms which meet all the above-said conditions.

Chapter VI

TASKS OF MANAGEMENT OF BIOLOGICAL SAFETY

Article 17.- Contents of state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms

1. Formulating and promulgating strategies, mechanisms, policies, plans and legal documents on, genetically modified organisms; products and goods originating from genetically modified organisms;

2. Building and developing a system of information and database on biological safety of genetically modified organisms; products and goods originating from genetically modified organisms;

3. Evaluating the registration of assay, release, production, trading, use, export, import, storage and transportation of genetically modified organisms; products and goods originating from genetically modified organisms; granting and withdrawing certificates and permits relating to biological safety of the above-said objects;

4. Conduct training, propaganda and education to raise the awareness of genetically modified organisms, products and goods originating from genetically modified organisms among organizations and individuals;

5. Undertaking international cooperation and implemen-ting treaties on genetically modified organisms; products and goods originating from genetically modified organisms;

6. Inspecting and supervising the observance and implementation of the provisions of law on biological safety of genetically modified organisms; products and goods originating from genetically modified organisms.

Article 18.- Tasks of the Ministry of Natural Resources and Environment

1. Acting as the focal point of the Government for managing biological safety of genetically modified organisms; products and goods originating from genetically modified organisms, having the task of assisting the Government in performing the unified state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms throughout the country;

2. Formulating and submitting for submission or promulgating according to its competence strategies, mechanisms, policies, plans and legal documents on genetically modified organisms; products and goods originating from genetically modified organisms;

3. Organizing and directing the coordination of activities of concerned agencies in performing the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms;

4. Coordinating with concerned ministries and branches in conducting training, propaganda and education to raise the awareness of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms among organizations and individuals;

5. Receiving from concerned managing ministries, organizations and individuals and processing information and data on genetically modified organisms; products and goods originating from genetically modified organisms; building and developing a system of information and database

on biological safety of genetically modified organisms; products and goods originating from genetically modified organisms; acting as the focal point in exchanging information on this issue with the international community;

6. Supervising, inspecting and handling violations connected with genetically modified organisms; products and goods originating from genetically modified organisms.

Article 19.- Tasks of the Ministry of Science and Technology

1. Performing tasks of state management of scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms;

2. Formulating and submitting for submission or promulgating according to its competence mechanisms, policies and legal documents on scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms;

3. Providing guidance for organizations and individuals on procedures for, and specific conditions on, registration of scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms. Evaluating, selecting, approving and directing the implementation of programs, schemes and projects on scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms;

4. Building and developing potentials in service of scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms;

5. Regularly supplying information and data relating to genetically modified organisms; products and goods originating from genetically modified organisms to the Ministry of Natural Resources and Environment, the focal point of the Government in charge of this issue.

Article 20.- Tasks of ministries managing various branches or domains

1. General tasks of managing ministries

a/ Ensuring necessary conditions for activities of specialized agencies; building and enhancing the capacity of agencies expertising and evaluating biological safety of genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

b/ Implementing and directing activities of state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

c/ Formulating and promulgating according to their competence legal documents and branch standards on scientific research and technological development concerning genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

d/ Providing for the order, procedures and conditions for assessing risks of activities related with genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

e/ Designating specialized scientific agencies to supervise the process of assessing risks of activities related to genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

f/ Evaluating the registration of assay, release, production, trading, use, export, import, storage and transportation of genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

g/ Evaluating, granting and withdrawing certificates of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms; and preparing lists of genetically modified organisms, products and goods originating from genetically modified organisms permitted for production and trading within the scope of their respective management;

h/ Supervising and inspecting the observance and implementation of the provisions of law on biological safety of genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

i/ Directing the handling and remedy of risks and incidents caused to the environment and human health by activities related with genetically modified organisms; products and goods originating from genetically modified organisms within the scope of their respective management;

j/ Regularly supplying information and data relating to genetically modified organisms; products and goods originating from genetically modified organisms to the Ministry of Natural Resources and Environment, the focal point of the Government in charge of this issue.

2. Specific tasks of some ministries

a/ The Ministry of Agriculture and Rural Development shall perform the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in agriculture and forestry;

b/ The Ministry of Fisheries shall perform state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in the fisheries sector;

c/ The Ministry of Health shall perform the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in the health sector; biological safety and food hygiene and safety of genetically modified organisms; products and goods originating from genetically modified organisms used as pharmaceuticals, food or cosmetics.

d/ The Ministry of Industry shall perform the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in the industrial sector.

Article 21.- Tasks of People's Committees of provinces or centrally run cities

1. Performing the state management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms in their localities;

2. Conducing information, propaganda and education activities to raise the awareness of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms among organizations and individuals in their localities;

3. Coordinating with concerned ministries, branches, organization and individuals in properly implementing activities related to genetically modified organisms; products and goods originating from genetically modified organisms in their localities;

4. Formulating plans on areas for assay, production of genetically modified organisms; products and goods originating from genetically modified organisms in their localities;

5. Inspecting and supervising and handling violations in activities related to genetically modified organisms; products and goods originating from genetically modified organisms according to their competence in their localities.

Chapter VII

HANDLING OF VIOLATIONS

Article 22.- Handling of violations

1. Organizations and individuals that commit acts of violating this Regulation's provisions on management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms shall, depending on the nature and seriousness of their violations, be disciplined or administratively sanctioned; if causing any damage, they must pay compensate therefor according to the provisions of law.

In case of committing violations resulting in serious consequences, individuals shall be examined for penal liability according to the provisions of law.

2. Those who abuse their position and powers to violate the provisions of law on management of biological safety of genetically modified organisms; products and goods originating from genetically modified organisms shall, depending on the nature and seriousness of their violations, be disciplined or examined for penal liability; if causing any damage, they must pay compensate therefor according to the provisions of law.

Article 23.- Handling of violations in import activities

1. In a contract for import of genetically modified organisms; products or goods originating from genetically modified organisms into the Vietnamese territory, the importer must request the exporter to commit to paying compensation for damage caused by the use of his/her products or goods; commit to making technical and financial contributions to handling and remedying adverse consequences on human health, the environment and biodiversity in places where such risks have occurred.

2. Where the importer deliberately imports genetically modified organisms; products or goods originating from genetically modified organisms even though he/she has failed to reach agreement with the exporter on measures to ensure safety as provided and commitments to pay compensation for damage caused by possible incidents, he/she must compensate for damage caused to human health, the environment, biodiversity, economic or social activities by

the use of such imported products or goods and bear all expenses for handling and remedying consequences from genetically modified organisms. If causing serious consequences, the importing individual shall be examined for penal liability according to the provisions of law.

Chapter VIII

IMPLEMENTATION PROVISIONS

Article 24.- Implementation provisions

In the course of implementation of this Regulation, ministries, branches and localities should report on any contents which should be amended and/or supplemented to the Ministry of Natural Resources and Environment for sum-up and reporting to the Prime Minister for consideration and decision.

For the Prime Minister
Deputy Prime Minister
PHAM GIA KHIEM