



# REQUEST FOR CEO ENDORSEMENT/APPROVAL

PROJECT TYPE: MEDIUM SIZED PROJECT

THE GEF TRUST FUND

Submission Date: 01 October 2010

## PART I: PROJECT INFORMATION

GEFSEC PROJECT ID: 4103

GEF AGENCY PROJECT ID: 00566

COUNTRY (IES): Republic of Macedonia

PROJECT TITLE: Support for the Implementation of the National Biosafety Framework of the Republic of Macedonia

GEF AGENCY (IES): UNEP

OTHER EXECUTING PARTNER(S): Ministry of Environment and Physical Planning

GEF FOCAL AREA(S): BD

GEF-4 STRATEGIC PROGRAM(S): SP6 (see preparation guidelines section on exactly what to write)

NAME OF PARENT PROGRAM/UMBRELLA PROJECT: BIOSAFETY

Expected Calendar (mm/dd/yy)	
Milestones	Dates
Work Program (for FSPs only)	N/A
Agency Approval date	November 2010
Implementation Start	February 2011
Mid-term Evaluation (if planned)	July 2012
Project Closing Date	Jan 2014

### A. PROJECT FRAMEWORK (Expand table as necessary)

Project Objective: Implementation of the National Biosafety Framework in line with national priorities and obligations to the Cartagena Protocol on Biosafety								
Project Components	Indicate whether Investment, TA, or STA <sup>2</sup>	Expected Outcomes	Expected Outputs	GEF Financing <sup>1</sup>		Co-Financing <sup>1</sup>		Total (\$) c=a+ b
				(\$ a)	%	(\$ b)	%	
1. Stocktaking on biosafety in Macedonia	TA	The project design and execution fills gaps and completes the NBF thus allowing decisions on the safe use of modern biotechnology to be taken in line with CBP.	(a) A stocktaking assessment which analyses the current status of biotechnology and biosafety in Macedonia, in order to improve project design and targeting of project activities.  (b) Amended national policies connected to biosafety and prepared biosafety policy/strategy	9,350	61	6,000	39	15,350
2. Regulatory regime	TA	Legislative system for risk assessment/ risk	[a] Biosafety regulations approved	30,000	67	15,000	33	45,000

		management, handling of LMO applications in place	[b] Competent authorities (CA) and Scientific Advisory Committee (SAC) mandated					
3. Handling requests for authorization (including administrative processing for risk assessment and informed decision-making)	TA	Safe use of modern biotechnology is possible through full compliance of Macedonian biosafety legislation with the CPB and the corresponding regulations of the EU., administrative system for handling of applications, RA/RM is in place	I. Guidelines, methodologies and manuals on risk assessment and risk management prepared  ii. Training on procedures for risk assessment and risk management  iii. Internet portal functional for data collection, input and analysis for risk management and risk communication purposes National procedures required in order to use the Biosafety Clearing-House Mechanism and provide information to the Biosafety Clearing House in force	91,350	60	60,000	40	151,350
4. Follow-up mechanisms (monitoring of environmental effects and	TA	Macedonia has public confidence in biosafety regulatory	Outputs Laboratory equipment purchased and reference	125,600	81	30,000	19	155,600

enforcement: control and inspections)		system enhanced due to effective monitoring and surveillance of intentional and non-intentional LMO presence and use	<p>laboratories equipped to carry out LMO detection and monitoring</p> <p>Monitoring and inspection system for LMOs established, human resources for monitoring, inspections, border controls, compliance to Biosafety Law and the Protocol and emergency response improved</p> <p>Guidelines, methodologies and manuals on monitoring, inspections and emergency response prepared</p> <p>Registration system with unique identifiers to trace back LMOs established</p>					
5. Public awareness and participation	TA	Macedonia has a functional system for public awareness and participation established for biosafety and level of public awareness on biosafety and participation into implementation	<p>a. Public awareness action plan of NBF updated</p> <p>b. National BCH strengthened</p> <p>c. Increased raising public awareness through newsletters,</p>	89,000	82	20,000	18	109,000

		of NBF is improved	videos, brochures, website and ensuring that the public are consulted for their views. Best practices and lessons learnt disseminated.					
6. M&E				21,000	51	20,000	49	41,000
7. Project management				40,700	32	85,000	68	125,700
<b>Total Project Costs</b>				407,000		236,000		643,000

<sup>1</sup> List the \$ by project components. The percentage is the share of GEF and Co-financing respectively of the total amount for the component.

<sup>2</sup> TA = Technical Assistance; STA = Scientific & Technical Analysis.

**B. SOURCES OF CONFIRMED Co-financing FOR THE PROJECT** (expand the table line items as necessary)

<i>Name of Co-financier (source)</i>	<i>Classification</i>	<i>Type</i>	<i>Project</i>	<i>%*</i>
Project Government Contribution	Nat'l Gov't	In-Kind	236,000	100
<b>Total Co-financing</b>			236,000	100%

\* Percentage of each co-financier's contribution at CEO endorsement to total co-financing.

**C. FINANCING PLAN SUMMARY FOR THE PROJECT (\$)**

	<i>Project Preparation a</i>	<i>Project b</i>	<i>Total c = a + b</i>	<i>Agency Fee</i>	<i>For comparison: GEF and Co-financing at PIF</i>
GEF financing		407,000	407,000	40,700	447,700
Co-financing		236,000	236,000		236,000
<b>Total</b>		643,000	643,000	40,700	683,700

**D. GEF RESOURCES REQUESTED BY AGENCY (IES), FOCAL AREA(S) AND COUNTRY (IES)<sup>1</sup>**

<i>GEF Agency</i>	<i>Focal Area</i>	<i>Country Name/ Global</i>	<i>(in \$)</i>		
			<i>Project (a)</i>	<i>Agency Fee (b)<sup>2</sup></i>	<i>Total c=a+b</i>
		Republic of Macedonia	407,000	40,700	447,700
<b>Total GEF Resources</b>			407,000	40,700	447,700

<sup>1</sup> No need to provide information for this table if it is a single focal area, single country and single GEF Agency project.

<sup>2</sup> Relates to the project and any previous project preparation funding that have been provided and for which no Agency fee has been requested from Trustee.

**E. CONSULTANTS WORKING FOR TECHNICAL ASSISTANCE COMPONENTS:**

<i>Component</i>	<i>Estimated person weeks</i>	<i>GEF amount (\$)</i>	<i>Co-financing (\$)</i>	<i>Project total (\$)</i>
Local consultants*	48	10,900	35,200	46,100
International consultants*	40	101,300	0,0	101,300
<b>Total</b>	<b>88</b>	<b>112,200</b>	<b>35,200</b>	<b>147,400</b>

\* Details to be provided in Annex C.

**F. PROJECT MANAGEMENT BUDGET/COST**

<i>Cost Items</i>	<i>Total Estimated person weeks/months</i>	<i>GEF amount (\$)</i>	<i>Co-financing (\$)</i>	<i>Project total (\$)</i>
Local consultants*	144 weeks	<b>34,000</b>	<b>110,900</b>	<b>144,900</b>
International consultants*				
Office facilities, equipment, vehicles and communications*		<b>6,700</b>	<b>33,400</b>	<b>40,100</b>
Travel*				
Others**				
<b>Total</b>		<b>40,700</b>	<b>144,300</b>	<b>185,000</b>

\* Details to be provided in Annex C. \*\* For others, it has to clearly specify what type of expenses here in a footnote.

**G. DOES THE PROJECT INCLUDE A “NON-GRANT” INSTRUMENT?** yes  no

(If non-grant instruments are used, provide in Annex E an indicative calendar of expected reflows to your agency and to the GEF Trust Fund).

**H. DESCRIBE THE BUDGETED M & E PLAN:** The project M&E plan is consistent with the GEF Monitoring and Evaluation policy. The Project Results Framework presented in Appendix 4 includes SMART indicators for each expected outcome as well as mid-term and end-of-project targets. These indicators along with the key deliverables and benchmarks included in Appendix 6 will be the main tools for assessing project implementation progress and whether project results are being achieved. The means of verification and the costs associated with obtaining the information to track the indicators are summarized in Appendix 4&7. Other M&E related costs are also presented in the Costed M&E Plan and are fully integrated in the overall project budget.

**PART II: PROJECT JUSTIFICATION:** In addition to the following questions, please ensure that the project design incorporates key GEF operational principles, including sustainability of global environmental benefits, institutional continuity and replicability, keeping in mind that these principles will be monitored rigorously in the annual Project Implementation Review and other Review stages.

**A. STATE THE ISSUE, HOW THE PROJECT SEEKS TO ADDRESS IT, AND THE EXPECTED GLOBAL ENVIRONMENTAL BENEFITS TO BE DELIVERED:**

The richness and heterogeneity of species and ecosystems are the most striking features of the biodiversity of the Republic of Macedonia. This situation is a result of Macedonia's specific geographic position, climate, geology, geomorphology, hydrography, pedology and other characteristics, such as the changes which occurred during past geologic periods. A great number of relict species and ecosystems are the result of these changes, which continue to have an effect on the recent flora, fauna and fungi. According to recent data, the imposing number of more than 18,000 taxa of flora, fauna and fungi - 900 of which are endemics - express Macedonia's rich biodiversity. The presence of more than 260 different plant communities also shows the great diversity of ecosystems. Even though Macedonia's land area is relatively small, it exhibits a great diversity of relief forms and agricultural varieties and is not exempt from the global, regional and national processes which cause the loss of biodiversity. In spite of the fact that, on a national level, the components of biological diversity are in better condition than those of the more developed European countries, this should not be a mandate for satisfaction. On the contrary, it should be a challenge to be more deliberate in implementing activities focused on biodiversity conservation in its entirety. Techniques of modern biotechnology are viewed as a new and promising tool for crop improvement and novel uses of plants, animals, and microorganisms. Concerns about the safety of

LMO's to human health and the environment, however, moderate the rate of development and deployment of LMO products. For that purpose national biosafety systems are intended to serve as mechanisms for ensuring the safe use of biotechnology products without imposing unacceptable risk to human health or the environment, or unintended constraints to technology transfer. However, establishing a system for biosafety review has many facets and associated challenges, and, apart from defining national guidelines, will require investments in people responsible for implementing and managing the system. The rapid development of biotechnology over the past few decades has initiated a development of relevant legal biosafety frameworks. On the one hand the National Biosafety Framework is to ensure an adequate level of protection of human health and the environment from possible adverse effects resulting from the products of modern biotechnology, and on the other hand to provide a basis for public confidence and for legal certainty for research organizations and industry. In respect of the above, the unregulated introduction of products of modern biotechnology could lead to loss of wild and agricultural biodiversity and thus an operational biosafety framework with adequate capacity is required to ensure that the potential benefits of modern biotechnology can be captured in a fully legal and transparent manner.

- B. Describe the consistency of the project with national and/or regional priorities/plans: The desire to apply biotechnology safely has led the country to agree on measures that ensure the safe handling and use of living modified organisms (LMO's). Internationally-agreed measures designed to prevent adverse effects of LMO's on human health and biodiversity are laid out in a supplementary agreement to the Convention on Biological Diversity, known as the Cartagena Protocol on Biosafety. The Cartagena Protocol on Biosafety includes articles stating that parties should cooperate in developing and strengthening human resources and institutional capacity in biosafety. The need to build national systems for risk assessment and national biosafety frameworks is one of the priorities emerging from the Convention on Biological Diversity. The Republic of Macedonia has accessed the Convention on Biodiversity with the adoption of the Law on Ratification (Official Gazette of RM no. 54/97). The Law entered into force on 2 March 1998. As obligation to this convention the National Strategy and Action Plan for conservation of biodiversity was prepared and adopted in January 2004. In frame of this Action Plan the need for drafting a Law on LMO was underlined as well as the need to undertake ratification of the Cartagena Protocol on Biosafety. Acknowledging the significance of the modern biotechnology and biosafety, the Republic of Macedonia has signed the Cartagena Protocol on Biosafety in 2000, and has ratified on 14 June 2005. The project, "Implementation of the National Biosafety Framework (NBF)", aimed to support the country in meeting the obligations foreseen under the Protocol by providing the needed capacity building. Biosafety legislation was initially drafted in the scope of the UNEP/GEF Project on development of national biosafety frameworks (2003 - 2005), in a participatory manner and it was agreed that there was a need to prepare a full law to address biosafety issues in the Republic of Macedonia. For that purpose, a special working group was set up in 2007 to finalize the draft of the Law on Genetically Modified Organisms, taking into account the National Biosafety Framework, which was concluded with enactment of the Law in September 2008 (Official Gazette of Republic of Macedonia 35/08). However, the working group did not manage to complete the approximation of the complete biosafety legislation due to insufficient human and financial resources. Biosafety is an important topic in the negotiations for EU accession. Macedonia, as a Candidate Country to the EU, must synchronize its legislation with the corresponding EU Directives. One of the Macedonian priorities is the formulation of a national biosafety regulatory system and the setting up of its operational mechanism in accordance with the requirements of the EU (Directives 90/219 as amended and 2001/18) and of the Protocol. According to the National strategy for approximation in the environment (2008) within the systematization plan of the Ministry for Environment and Physical Planning, one Unit for implementation of the requirements according to the Law on GMOs, shall be established which is still on hold, due to lack of human capacity. The Food Directorate within the Ministry of Health is responsible for management of food that contains, or consists of GMO. According to the Book of rules for the special requirements for safety of food that contains or is produced from GMOs (Official Gazette of RM 78/08), the Food Directorate shall take samples from food for testing the presence of GMOs with support by the state food inspectors as part of their official controls. Samples should be sent for testing in the Laboratory of the Faculty for Agricultural Sciences and Food (University of Ss. Kiril and Metodij) as the Laboratory authorised by the Ministry of Health in 2006. However, this procedure is still in beginning phase of implementation and a great need of strengthening the capacities of the state food inspectors for implementation of this process has been identified. Establishment of the State Laboratory for LMO testing is still in planning and current laboratories capacities are being assessed for need of additional equipment in order to perform LMO testing. This project will strengthen the all of the above capacities in term of improvement of the monitoring process of LMO. A Commission for Management of GMOs and a Scientific Committee for GMO were established by the Decision for establishing of the Commission for management of GMOs and Decision for

establishing of the Scientific Committee for GMOs in February 2009. (Official Gazette of Republic of Macedonia 11/09). A Strategy for Agricultural Development was prepared by the Ministry for Agriculture, Forestry and Water Economy in collaboration with the Macedonian Academy of Sciences and Art in 2001. Although the strategy has identified that one of the general objectives is the rational management of the human and natural resources in direction of reducing the release of non-safe substances in the environment, there are no planned/defined measures or activities for implementation of this in the context of LMOs.

- C. DESCRIBE THE CONSISTENCY OF THE PROJECT WITH [gef strategies](#) AND STRATEGIC PROGRAMS:** The project belongs to the GEF Biodiversity Focal Area. Biosafety is one of the priority areas of the GEF-4 Strategic Programme under SO3: To safeguard biodiversity stating that “In order to safeguard biodiversity, countries require management systems and frameworks that have the capacity to detect, exclude, eradicate, control and effectively manage introduced organisms that pose a risk to biodiversity. Through this strategic objective, GEF will help build country capacity to implement the Cartagena Protocol on Biosafety.” Therefore, “Building Capacity for the Implementation of the Cartagena Protocol” is included as SP6 of GEF-4 Strategic Programme. Furthermore, GEF Council adopted the GEF Strategy for Financing Biosafety (GEF C.30/8/Rev.1) to help build the capacity of eligible countries<sup>1</sup> to implement the Cartagena Protocol on Biosafety through activities at the national, sub-regional and regional levels. Capacity building is a key prerequisite for the effective implementation of the Cartagena Protocol on Biosafety (CPB). In order to be able to implement their obligations, Parties to the CPB need appropriate institutional mechanisms and infrastructure, well-trained human resources, adequate funding as well as easy access to relevant information. At its first meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol on Biosafety, adopted in Annex 1 of decision BS-I/5, an Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety. At its second meeting, COP-MOP in decision BS-II/3 adopted terms of reference for a comprehensive review of the Action Plan and invited Governments and relevant organizations to submit information regarding the progress and effectiveness in their implementation of the Action Plan as well as suggestions on the desired revisions. The Secretariat prepared, on the basis of the submissions received, a synthesis paper including strategic recommendations for a possible revision of the Action Plan. At its third meeting, COP-MOP in decision BS-III/3 adopted an updated version of the Action Plan. Therefore the project is in line with GEF strategies and CPB priorities.
- D. JUSTIFY THE TYPE OF FINANCING SUPPORT PROVIDED WITH THE GEF RESOURCES.** No PPG was requested.
- E. OUTLINE THE COORDINATION WITH OTHER RELATED INITIATIVES:** The Republic of Macedonia has executed the UNEP/GEF Project on Development of Biosafety Frameworks between 2003-2005. National Biosafety Framework was prepared at the end of the development project including draft law on biosafety ensuring follow-up of the outputs of the project. The follow-up steps were toward the finalization and approval of the draft law on biosafety, establishment of BCH for Macedonia and the implementation of the NBF. Actions and activities given below are the main requirements for implementation of the NBF: (i) Preparation of regulations under the biosafety law; (ii) Capacity building to meet risk assessment and management requirements including training of technical staff and establishment of laboratories and reference laboratory; and (iii) Operation of the national data base and setting up the link to the national Biosafety Clearing House. As a part of the EU financed CARDS Programme in 2006, a GAP analysis of the draft Law on GMOs was prepared which was of great support to the Working Group for the finalization of the this Law before its enactment in 2008. Macedonia currently is implementing the UNEP/GEF Project on strengthening the capacity and effective participation to the Biosafety Clearing House (BCH) with the main objective to set up the national BCH as a mechanism to contribute to implementation of the Cartagena Protocol on Biosafety. As planned in frame of the Project following activities are ongoing: - Setting up and testing of the National BCH web site: [www.biosafety.org.mk](http://www.biosafety.org.mk) ; - Organization of four national workshops on topic for presentation and promotion of the BCH as mechanism for implementation of the CPB. However, during this Project the country will still not be able to complete the operationalization of its national data base for the process of handling requests for authorization. Currently, very other few initiatives are being implemented in the related sectors in Macedonia. According to the GMO national legislation, three Governmental institutions are leading the implementation on biosafety procedures. In this respect there is some collaboration with following ongoing projects: Under the Food Directorate, Ministry of Health, there is a regional project funded by the Swedish Government through the Swedish International Development Agency (SIDA) aimed at “Regulatory and quality infrastructure development for Food Safety and Quality in South East Europe (Macedonia)”. As this Project is regional it is being implemented in Bosnia & Herzegovina as well as Macedonia. The projects started in February 2008 and will end in December 2011. However this project is not covering any activities towards specifically

strengthening the capacity for implementation of biosafety procedures in the country. According to the above, there are no overlapping in project objectives, but collaboration in terms of reaching quality implementation of the biosafety legislation will be built into this project. In addition, so far there are no planned introductions of modern biotechnology, especially field trials and no collaborative work with ICARDA so far, or any other international center where modern biotechnology is in use.

**F. DISCUSS THE VALUE-ADDED OF GEF INVOLVEMENT IN THE PROJECT DEMONSTRATED THROUGH incremental reasoning:** Today, Macedonia has poor capacity for establishing a proper national legislation and the related management system on Biosafety as shown by the delay in implementation of the Law on GMOs. This project will help the Working Group on the law and also allow the use of foreign experts on biosafety legislation. The project will also involve more local specialists in the development of appropriate policies, thus promoting integration of Biosafety into broader policy and regulatory frameworks, This project aims therefore at supporting Macedonia in meeting the obligations foreseen under the Cartagena Protocol on Biosafety. In particular, with respect to the requirements coming from Articles 1 and 2 of the Cartagena Protocol, Macedonia needs to revise the draft NBF developed in the UNEP/GEF Project on Development of NBFs and set up a comprehensive framework for biosafety, in order to put in place appropriate legal and regulatory systems to assess any possible impact on the environment and human health and ensure their adequate protection in the field of safe transfer, handling, and use of LMO, by the means of proper infrastructure and human potential. Relevant regulations, based on the Cartagena Protocol on Biosafety and the EU Directives, will assure proper implementation of the Law on GMOs. This Project will ensure harmonising the national regulatory regime in order to meet the international obligations under the Cartagena Protocol. Within the context of the project, the baseline includes the activities carried out at domestic level with respect to each specific project component; the increment includes the activities proposed under this project proposal for the purpose of meeting the requirements of the Cartagena Protocol, to be financed through the GEF contribution and national co-financing. These activities will be based on the following: The draft National Biosafety Framework was completed in 2005, when the national administrative, legislative and institutional status and capacity needs with regard to biosafety were determined at that time. Since then, there are some developments and changes in the administrative and institutional status. Therefore, component 1 (stocktaking exercise) is required to update information on stakeholders and gaps on biosafety for effective planning and implementation of the other components of the project. The Law on GMO forms the basis for biosafety regulatory regime in Macedonia. Adoption of the draft law in 2008 was delayed because of the heavy agenda of Macedonian National Assembly. Therefore, there is a requirement now, to gain the attention of senior officials and members of Sector for European Approximation process to facilitate the preparation of the secondary legislation. Without the project and activities under component 2, this process may be further delayed which would be weaken the enforcement of the regulative framework and implementation of Law on GMO and the CPB. The institutional baseline for handling of request, risk assessment, risk management, monitoring and inspections constitutes laboratories with the potential to be included in the biosafety network and these laboratories also presents as research institutes. Administrative and technical staff of the competent authorities constitutes a basis to some extent for human resources for handling of requests, risk assessment, decision-making and risk management. However, the current administrative and technical capacity of the Ministry of Environment and Physical Planning and other related institutions is not enough to comply with the provisions of CPB and Law on GMO. Without adequate human resources (both in quality and in quantity), notifications cannot be evaluated in an appropriate manner and the system cannot function well enough to respond to notifications within the appropriate time periods. Without the 3rd component of the project, determination and handling of illegal movements and release of LMOs would not be possible and may result with damage on biodiversity. There are no approved LMOs in Macedonia yet due to lack of functional legal and administrative biosafety system, therefore there is also no operational monitoring and inspection system for LMOs. Monitoring and inspection system is the priority issue for Macedonia as being so rich of genetic origins and diversity for crops in the region. The current technical capacity required to be strengthened to meet fully the obligations of CBD and CPB as well as enforcement of the Law on GMO. Mandating of particular laboratories for LMO detection and training of technical staff on LMO detection and identification is a key capacity need in order to allow an effective monitoring and inspection system to regulate transboundary movements and environmental release of LMOs. The plan on public awareness, education and participation was prepared in the scope of the development of NBF project and by the BCH Project was simply continued in line of promoting the national BCH, but could not be fully operational yet due to lack of resources. The project would serve sustainable and effective system for public awareness, education and participation on biosafety. Consequently, baseline for biosafety would

lead to illegal introduction of LMOs in Macedonia, weak implementation of CPB and possible environmental damages due to weak monitoring and inspection.

**G. INDICATE RISKS, INCLUDING CLIMATE CHANGE RISKS, THAT MIGHT PREVENT THE PROJECT OBJECTIVE(S) FROM BEING ACHIEVED AND OUTLINE RISK MANAGEMENT MEASURES:** The most important risk to the project is that the biosafety strategy will not be approved due to change of govt., political instability etc. For that purpose the activity 1.1 (preparation of the Stocktaking Assessment ) for national biotechnological status and strategy for development of capacity at public and private level will be carried out in order to identify the needs for ensuring the safe use, import and export of living modified organisms as required in the Protocol). Another important risk is that the approval of the secondary legislation for implementing the Law on GMO (OG of RM 35/08) is delayed. Since this process is dependent on the Macedonian National Assembly (external factor), the activity 2.1. (Organization of meetings of senior officials to prepare approval/enforcement of biosafety regulation) is foreseen to facilitate approval of the regulation. Training of trainers and preparation of guidelines and manuals will provide sustainability of human resources in biosafety laboratories and institutes as included under component 3 and 4 of the project. Close collaboration and cooperation between institutions is an important factor in the successful implementation of the project. In addition to the Project Coordination Committee, the Activity 3.5 (Training of Customs personnel on biosafety) and 4.2 (Training of Judiciary officials on dispute settlement, handling of court cases and enforcement) will serve sustainability of institutional collaboration and cooperation both during and after the project.

**H. EXPLAIN HOW COST-EFFECTIVENESS IS REFLECTED IN THE PROJECT DESIGN:** In general the cost-effectiveness will arise from being able to build on capacity already put in place by previous GEF support for NBF development and establishment of the national BCH, by ensuring continuation of the objectives. For the Republic of Macedonia, agriculture is the third largest economic sector, after services and industry, and is an important part of the economy in terms of contribution to GDP, to external trade, employment, incomes, and to the food self-sufficiency of rural populations. Its share in the overall GDP (nominal and real) has remained relatively stable, and has presented a barrier for the socioeconomic and structural changes in industry and other sectors of the economy. Since agricultural production in Macedonia is carried out in small enterprises using rather low agricultural inputs, it also provides a suitable environment for the conservation of wild species through the farmer in the rural sector. But this structure also increases risks of LMOs to agrobiodiversity. Macedonia has difficulties in management of activities involving LMOs with respect to conservation of biological diversity, since there is no strong biosafety regulatory regime in place, and the country could not finalize the administrative procedures and proceed with the administrative, legislative and institutional gaps to prohibit and penalize illegal movements of LMOs. Therefore, Macedonia would not be able to make safe use of modern biotechnology without a strong biosafety regime in place. During the UNEP/GEF project on development of NBF supported by internal resources, technical and human resource capacity of competent authorities were supported. Training of trainers is a key activity in the project for cost effectiveness in terms of technical capacity and will provide sustainability of the biosafety system. The ability of safe use of modern biotechnology will contribute conservation of biological diversity, particularly genetic resources important for food and feed, meeting obligations of Macedonia under other multilateral environmental conventions.

### **PART III: INSTITUTIONAL COORDINATION AND SUPPORT**

- A. INSTITUTIONAL ARRANGEMENT:** GEF Implementing Agency is UNEP, Executive Agency is the Agency of Environment within the Ministry of Environment and Physical Planning of the Government of Republic of Macedonia (see Section 5 and Appendix 10 of UNEP Prodoc)
- B. PROJECT IMPLEMENTATION ARRANGEMENT:** The project will be executed by the Ministry of Environment and Physical Planning, Agency of Environment, and project funds will be transferred on governmental account allocated for this project specifically. The project will be implemented through a NCC and managed by the National Project Coordinator, who will be assigned by the NEA, in consultation with UNEP.

**PART IV: EXPLAIN THE ALIGNMENT OF PROJECT DESIGN WITH THE ORIGINAL PIF:** Reallocation was arranged in component A: i.e. increased for 3,350 USD in order to provide more in-depth assessment and preparation of the stocktaking report. For that purpose, the necessary amount was withdrawn from component C. From component D the amount of 4,000 USD was reallocated to component E for strengthening the public awareness component in term of providing trainings for educators and 700 USD to component F for supply of necessary office equipment.

**PART V: AGENCY(IES) CERTIFICATION**

This request has been prepared in accordance with GEF policies and procedures and meets the GEF criteria for CEO Endorsement.

Agency Coordinator, Agency name	Signature	Date (Month, day, year)	Project Contact Person	Telephone	Email Address
Maryam Niamir-Fuller Director UNEP Division of Global Environment Facility (GEF) Coordination		1 October 2010	Alex Owusu- Biney, UNEP Task Manager	+254-762- 4066	Alex.owusu- biney@unep.org

## ANNEX A: PROJECT RESULTS FRAMEWORK

Objectives and Outcomes/Outputs	Objectively Verifiable Indicators	Baseline	Indicators	Means of Verification	Important Assumptions
<p><b>Objective:</b> Implementation of the National Biosafety Framework in line with national priorities and obligations to the Cartagena Protocol on Biosafety.</p>	<p>By the end of the project, Macedonia has in place biosafety policy, legislative framework and administrative framework for implementing CPB.</p>	<p>Draft NBF was prepared during 2003 - 2005</p>	<p>By 2013 updated NBF in place and adopted by the government</p>	<p>All components of the National Biosafety Framework are in place and functioning, including (draft) policy of biosafety and legislation drafted/agreed/adopted, responsible authorities nominated and available in project website/BCH and UNEP ANUBIS.</p>	<p>Government supports the NBF, stability in policy and government, no delays in project implementation, especially in regards to the legal component</p>
<p><b>Outcome A:</b> Assessment of the status of modern biotechnology and biosafety and national capacity needs assessment and preparation of biosafety strategy</p>					
<p><b>Outputs:</b></p> <p>(a) A stocktaking assessment which analyses the current status of modern biotechnology and biosafety in Macedonia, in order to improve project design and targeting of project activities.</p> <p>(b) Amended national policies connected to biosafety and prepared biosafety policy/strategy</p>	<p>(a) Stocktaking report is produced, containing an assessment of current resources, infrastructure, legislation in place, as well as analysis of existing gaps.</p> <p>(b) Biosafety policy drafted/agreed/adopted, other policies amended</p>	<p>a) Some information is contained in draft NBF, but no comprehensive information available</p> <p>b) Some elements of biosafety is contained on food safety policy, and policy for environment protection but needs updating and no elements of biosafety are included in the agricultural (phytosanitary and veterinary) policy</p>	<p>a) By early 2011, stocktaking report is finalized</p> <p>b) By 2011 all relevant policies are analyzed by experts, gaps identified. By 2012 collection of samples from other countries, analyzing them and amendments proposals. By 2013 policies updated and amended in regard of biosafety</p>	<p>a) All components of the National Biosafety Framework are reviewed and are elaborated into the project work-plan, incorporating the findings of the stocktaking assessment. NPC to include stocktaking report to the periodic reporting (ANUBIS).</p> <p>(b) NPC to include draft policy on biosafety and amended policy papers to project website</p>	<p>a) Government agrees to change policy in food safety sector, phytosanitary sector, as well as the environmental protection in regard of biosafety and provides financial or in kind support.</p> <p>b) Good cooperation between other sectors connected to biosafety.</p>
<p><b>Outcome B</b> Legislative system for risk assessment/ risk management, handling of LMO applications in place</p>					
Outputs:					

(a) Biosafety regulations approved	a) Secondary legislation prepared, amended and discussed with stakeholders representatives and approved	a) Primary act was adopted in 2008, but it is lacking secondary legislation.	a) By 2011, analysis of needs for secondary legal acts. By 2012 drafting legal acts. By 2013 adopted.	a) The corresponding regulations are approved by the government, published and distributed in the official gazette and official web pages of the government and national biosafety portal and BCH.	a) Good cooperation between different sectors resulting in agreed legislation and administrative system.
[b] Competent authorities (CA) and Scientific Advisory Committee (SAC) mandated	b) A multi-sectorial working group is set up to provide assistance and guidance to the development of the regulatory regime	b) Ministry of Environment nominated as CA for GMOs. SAC set up, but they are lacking the work plan	b) By 2011, CAs and SAC have their workplan	b) Names and coordinates of CA and SAC are available in project website and BCH.	b) Good cooperation between different sectors resulting in agreed legislation and administrative system.

**Outcome C:** Safe use of modern biotechnology is possible through full compliance of Macedonian biosafety legislation with the CPB and the corresponding regulations of the EU., administrative system for handling of applications, RA/RM is in place

<p>Outputs:</p> <p>a).Guidelines, methodologies and manuals on risk assessment and risk management prepared</p> <p>b).Training on procedures for risk assessment and risk management</p> <p>c).Internet portal functional for data collection, input and analysis for risk management and risk communication purposes National procedures required in</p>	<p>a) Creation of technical guidelines for handling of requests (including Risk Assessment/Risk Management guidelines)</p> <p>b) Training for risk assessment and risk management for personnel from CAs and scientific institutions organized</p> <p>c) Maintenance of functional national biosafety portal - BCH for collection of data, input and analysis for risk management and risk communication purposes Preparation of</p>	<p>a) No manuals available in local language.</p> <p>b) Personnel are not trained in regard of RA/RM.</p> <p>c) No internet portal available</p>	<p>a) By 2013, manuals drafted and published.</p> <p>b) By 2013, 11 training events performed to train relevant personnel.</p> <p>c) By 2012, internet portal functional.</p>	<p>a) Guidelines available Internal manuals available in project website. Summary available on the BCH. Printed Publications, Manuals available, copies sent by NPC</p> <p>b) Training reports sent by NPC</p> <p>c) Information documents available in local languages in project website, copies sent by NPC. National BCH connected to main portal of BCH</p>	<p>a-b) Institutional mechanisms and entities for administering biosafety, including competent national authorities and their responsibilities, willing to work and knowing their responsibilities. Decision making system and administrative procedures, and Inter-agency communication and coordination adopted by government and accepted by public and stakeholders. .</p> <p>c) Ministry is able to provide good internet connection to enable use of BCH and internet portal.</p>
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order to use the Biosafety Clearing-House Mechanism and provide information to the Biosafety Clearing House in force	national procedures required in order to use the BCH mechanism and provide information to the BCH				
<b>Outcome D:</b> Macedonia has public confidence in biosafety regulatory system enhanced due to effective monitoring and surveillance of intentional and non-intentional LMO presence and use					
<b>Outputs</b> a) Laboratory equipment purchased and reference laboratories equipped to carry out LMO detection and monitoring  b) Monitoring and inspection system for LMOs established, human resources for monitoring, inspections, border controls, compliance to Biosafety Law and the Protocol and emergency	a). detailed outline of the laboratory equipment necessary for complementing the existing laboratory at the selected institution in order to become compliant with CP and technical requirements for the functioning of an LMO laboratory.  b) Organization of national and international training workshops for immediate stakeholders on monitoring, producing training reports Relevant staff	a) Republic of Macedonia has only one laboratory for testing and identification of GMOs in food. In 2006, the Ministry for Health, Directorate for food, had granted authorization for testing, control of GMO in food to the Laboratory for Biochemistry and Molecular Biology at the Faculty of Agriculture and Food. Second Laboratory is within the Macedonian Academy of Sciences and Art as part of the Research Institute for Genetic Engineering relevant for GMO detection in plants. Both laboratories have only started with process of establishing of quality system (ISO 17025) and accreditation of laboratory.  b) No staff trained for monitoring and evaluation	a) By 2013, national referent laboratory/ies fully equipped  b) By 2013, three trainings organized for monitoring staff  c) By 2013, technical guidelines published	a) NPC to include the list of needed equipment to the regular reporting, as well as list of purchased equipment  b) NPC to include workshop reports, manuals etc to regular reporting.  c) Training manuals and	a) The process of accrediting and setting quality control will be finalized. Government and academia will provide sufficient money for maintaining the labs and equipment.  b-d) Good cooperation between different institutions to enable to implement of emergency measures for unintentional movements, inspection procedures and control measures as well as in the mechanism for detecting

response improved	of responsible agencies are trained on monitoring and evaluation and have been issued respective certification			technical documents for monitoring and inspection available in project website, copies sent by NPC Monitoring and inspection plans available in national websites of relevant authorities.	unintentional or illegal LMO movement. C.
c) Guidelines, methodologies and manuals on monitoring, inspections and emergency response prepared	c) Technical guidelines for monitoring developed and distributed to responsible personnel	c) No technical guidelines available	d) By 2013, registration system established and functional	d) Address of registration system sent by NPC	
d) Registration system with unique identifiers to trace back LMOs established	d) Establishment of registration system with unique identifiers to trace back LMOs established. Monitoring and inspection are included in work plan and strategies of relevant enforcement agencies	d) No registration system			
<b>Outcome E: Macedonia has a functional system for public awareness and participation established for biosafety and level of public awareness on biosafety and participation into implementation of NBF improved</b>					
Outputs: a) Public awareness action plan of NBF updated	a) Public awareness action plan and public service campaign strategy	a) Public awareness plan and campaign strategy was drafted in 2003-2005, but need updating	a) By 2012, awareness plan and campaign strategy updated	a) Action plan and strategy available in project website Access records of the national BCH.	A. a - d) Public will better understand biosafety and participate actively in campaigns and other activities, no opposition from their side. No interest group will be working against the project activities. Government will cooperate in the sustaining the awareness activities
b) National BCH strengthened	b) Number of records on the nBCH.	b) Currently, only general information available on national BCH	b) By 2013. National BCH functional	b) Country information available on the BCH central portal	
c) Increased raising public awareness through	c) Number of people trained to continue tasks;	c) Lack of consultation with public for views on biosafety.	c) By 2013 developed media coverage by preparation of written and video	c) Feedbacks and suggestions from workshop participants are recorded and	

<p>newsletters, videos, brochures, website and ensuring that the public are consulted for their views. Best practices and lessons learnt disseminated.</p>	<p>workshop reports</p>		<p>material on biosafety</p>	<p>available in project website. List of workshop participants and agenda sent by NPC</p>	<p>and taking it over after the end of the project.  B.</p>
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**ANNEX B: RESPONSES TO PROJECT REVIEWS** (from GEF Secretariat and GEF Agencies, and Responses to Comments from Council at work program inclusion and the Convention Secretariat and STAP at PIF)

Questions	Secretariat Comment at PIF/Work Program Inclusion	Response made a PIF stage
<p>9. Is the project design sound, its framework consistent &amp; sufficiently clear (in particular for the outputs)?</p>	<p>Please address the following issues:</p> <ol style="list-style-type: none"> <li>1. Please provide an objective under A. Project Framework.</li> <li>2. Is the budget allocation for component 4 enough to cover the Lab Equipment, Monitoring Systems, and Guidelines? To what extent, similar documentation produced in neighboring countries be adapted to the country specific needs?</li> <li>3. Unless GMO is used as part of an official name (i.e. a Law), please use "LMOs" only.</li> </ol>	<p><b>Justification:</b> Objective: D. Confirming that budget allocation for component 4 is enough to cover the Lab equipment, Monitoring Systems and Guidelines. E. GMO is used as part of the an official name in the National Law on GMO's (OG of RM 35/08)</p> <p><b>Change made in PIF:</b> N/A</p>
<p>13. Does the project take into account potential major risks, including the consequences of climate change and includes sufficient risk mitigation measures?</p>	<p>09-24-09 Since the most important risk is the government and political instability, please elaborate on the timing of this proposal. Is the balance of power in the Macedonia National Assembly in favor of reviewing and approving the secondary legislation for the implementation for the Law on GMO?</p>	<p><b>Justification:</b> Macedonian National Assembly is not reviewing and approving the secondary legislation for the implementation of the Law on GMO, but only the ministerial level i.e. Government.</p> <p><b>Change made in PIF:</b> N/A</p>
<p>15. Is the type of financing provided by GEF, as well as its level of concessionality, appropriate?</p>	<p>09-24-09 Macedonia is requesting \$407,000 only.  Is this amount sufficient to achieve the proposed outputs?  The allocation for Group countries was \$1.1M initially, and then increased. What impedes to increase the request for GEF funding?</p>	<p><b>Justification:</b> This amount is sufficient to achieve the proposed outputs.</p> <p><b>Change made in PIF:</b> N/A</p>

**ANNEX C: CONSULTANTS TO BE HIRED FOR THE PROJECT USING GEF RESOURCES**

<i>Position Titles</i>	<i>\$/ person week*</i>	<i>Estimated person weeks**</i>	<i>Tasks to be performed</i>
<b>For Project Management</b>			
Local			
NPC	236	144	project coordination
International			
Justification for Travel, if any:			
<b>For Technical Assistance</b>			
Local			
national consultants	993	13	training, lawyers
International			
Expert for gap analysis	2,000	1	preparation of gap analysis
Training experts	2,459	37	trainings on risk assessment, public awareness, legal trainings on biosafety procedures, LMO monitoring and inspection procedures, Safety requirements and procedures for LMOs contained use, deliberate release and commercial use, Transboundary movement of LMO and the Cartagena Protocol on Biosafety, CP and how to meet minimum requirements, international obligations of the country, regulatory instruments related to biosafety in the country
Experts for preparation of technical guidelines	2,334	6	Develop appropriate rules for enforcement of performing risk assessment and management for implementing the LMOs Act, drafting of RA national guidelines and procedures, Develop guidelines and rules for monitoring (in cooperation with other countries)
Justification for Travel, if any:			

\* Provide dollar rate per person week. \*\* Total person weeks needed to carry out the tasks.

**ANNEX D: STATUS OF IMPLEMENTATION OF PROJECT PREPARATION ACTIVITIES AND THE USE OF FUNDS**

**A. EXPLAIN IF THE PPG OBJECTIVE HAS BEEN ACHIEVED THROUGH THE PPG ACTIVITIES UNDERTAKEN.**

No PPG was requested

**B. DESCRIBE FINDINGS THAT MIGHT AFFECT THE PROJECT DESIGN OR ANY CONCERNS ON PROJECT IMPLEMENTATION, IF ANY:**

**C. PROVIDE DETAILED FUNDING AMOUNT OF THE PPG ACTIVITIES AND THEIR IMPLEMENTATION STATUS IN THE TABLE BELOW:**

<i>Project Preparation Activities Approved</i>	<i>Implementation Status</i>	<i>GEF Amount (\$)</i>			<i>Uncommitted Amount*</i>	<i>Co- financing (\$)</i>
		<i>Amount Approved</i>	<i>Amount Spent To date</i>	<i>Amount Committed</i>		

<b>Total</b>						

\* Any uncommitted amounts should be returned to the GEF Trust Fund. This is not a physical transfer of money, but achieved through reporting and netting out from disbursement request to Trustee. Please indicate expected date of refund transaction to Trustee.

**ANNEX E: CALENDAR OF EXPECTED REFLOWS**

Provide a calendar of expected reflows to the GEF Trust Fund or to your Agency (and/or revolving fund that will be set up)