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Программа Организации Объединенных Наций по окружающей среде | برنامج الأمم المتحدة للبيئة

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UNEP

PROJECT DOCUMENT

SECTION 1: PROJECT IDENTIFICATION

1.1 Project title: Capacity Building for the Developmen of the National Biosafety Framework of Macedonia

1.2	**Project number:**	GFL/ PMS:
1.3	**Project type:**	MSP
1.4	**Trust Fund:**	GEF
1.5	**Strategic objectives:**	
	GEF strategic long-term objective:	BD3
	Strategic programme for GEF IV:	SP6
1.6	**UNEP priority:**	Environmental governance
1.7	**Geographical scope:**	National
1.8	**Mode of execution:**	External
1.9	**Project executing organization:**	Ministry of Environment and Physical Planning
1.10	**Duration of project:**	36 months Commencing: February 2011 Completion: January 2014

11.1 Cost of project	**US$**	**%**
Cost to the GEF Trust Fund	407,000	63
Co-financing	236,000	37
Cash		
Sub-total		
In-kind		
Government contribution	236,000	37
Sub-total	236,000	
Total	643,000	**100**

1.12 Project summary

Macedonia aims to complete the development of, and initiate implementation of, the National Biosafety Framework. In this respect, the project objective is to provide support for implementation of the National Biosafety Framework in line with national priorities and international obligations under the Cartagena Protocol on Biosafety. Thus, project will contribute to building national capacity for institutional strengthening, not only to fulfill the requirements under the Cartagena Protocol, but also to fulfill the requirements for eventual harmonisation with EU biosafety legislation, by implementation of the following:

- assessment of the status of modern biotechnology, national capacity needs assessment for biosafety, and preparation of a biosafety strategy,
- finalisation of the biosafety regulatory regime,
- pilot testing of the administrative system,
- putting in place adequate systems for monitoring and enforcement, and
- raising public awareness of biosafety and improving public particpation in biosafety decision-making process.

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ACRONYMS AND ABBREVIATIONS

BCH	Biosafety Clearing House
CA	Competent Authorities
CPB	Cartagena Protocol on Biosafety
CBD	Convention on Biological Diversity
EC	European Commission
EOU	Evaluation and Oversight Unit
GMO	Genetically Modified Organisms
GEF	Global Environment Facility
EU	European Union
LMO	Living Modified Organisms
M&E	Monitoring and Evaluation
MoEPP	Ministry of Environment and Physical Planning
MSP	Medium Size Project
NBC	National Biosafety Committee
NBF	National Biosafety Framework
NCC	National Coordination Committee
NGO	Non-Governmental Organization
OG	Official Gazette
PIR	Project Implementation Review
RA	Risk Assessment
RM	Risk Management
SAC	Scientific Advisory Commission
SMART	Specific, Measurable, Attainable, Realistic and Timely
TV	Television
UNEP	United Nations Environment Programme

SECTION 2: BACKGROUND AND SITUATION ANALYSIS (BASELINE COURSE OF ACTION)

2.1 Background and context

1. Article 2 of the Cartagena Protocol on Biosafety states that: "*Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol*" and "*The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health*". Operationally, this means that Parties to the Protocol have to:

- provide sufficient capacity for handling of notifications, risk assessment, risk management and socio-economic consideration,
- prevent unintentional and/or illegal transboundary movements, to implement emergency measures,
- comply with the obligations on handling, transport, packaging and identification,
- participate in the biosafety clearing-house mechanism, and
- raise awareness of public on biosafety issues and ensure their participation into relevant decision-making processes, in order to provide effective sharing of relevant information.

2. As a Party to the Convention on Biological Diversity (CBD), as well as 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. In the Republic of Macedonia, the Ministry of the Environment and Physical Planning (MoEPP) is the state competent authority responsible for implementation of the Cartagena Protocol on Biosafety (CPB).

3. After signing the CPB, Macedonia lacked any legislative, administrative, institutional and technical procedures on biosafety and would not be able to take any decisions on use of modern biotechnology, even for a field trial. In the period from 2002 to 2005, Macedonia participated in the UNEP/GEF global project on "Development of National Biosafety Frameworks". The general components of the draft National Biosafety Framework developed through this project comprised the following:

- a biosafety policy,
- a regulatory regime,
- a system to handle notifications or requests for authorizations,
- mechanisms for monitoring and enforcement,
- mechanisms for promoting and facilitating public awareness, education and participation.

4. These components were elaborated in a draft Law on GMO which was also prepared during the project.

5. From the year of entry into force of the Protocol until the present time, Macedonia's primary goal has been to harmonize national legislation, in every area, with the European Union legislation. This process had started on 1 December 2001 and it has intensified, especially from 2004 when Macedonia became an accession country to the EU. Thus, Macedonian legislation on GMOs is based on transposition and implementation of the EU

6. Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms and Directive2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, some provisions from Cartagena Protocol on Biosafety are transposed by the GMO Law on Genetically Modified Organisms (Official Gazette No. 35/2008).

7. This GMO Law regulates the management of genetically modified organisms and combinations of genetically modified organisms, and products containing genetically modified organisms and/or consisting of or derived from a combination of genetically modified organisms, including therein genetically modified organisms as a product, measures for prevention and reduction of possible adverse effects on human health and on the environment as a consequence of the contained use of genetically modified organisms, deliberate release into the environment of genetically modified organisms or placing on the market of products containing genetically modified organisms and/or consisting of or derived from a combination of genetically modified organisms, including therein genetically modified organisms as a product, as well as transboundary movement of genetically modified organisms and of products containing genetically modified organisms and/or consisting of or derived from a combination of genetically modified organisms, including therein genetically modified organisms as a product.

8. However, administrative and institutional arrangements in line with the Law on GMO and the Protocol are still not fully established and there is a need to strengthen human resources capacity for effective implementation of the Law. There is also a need to strengthen the capacity of two laboratories for LMOs detection. In addition, as important issue is the improper information to the public due to the substantially raised promotion by national NGOs, private sector and media.

2.2. Global significance

9. 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 capacity building of institutions and persons responsible for implementing and managing the system. The rapid and exponential development of modern biotechnology over the past 20 years 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 building and for providing 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.

2.3. Threats, root causes and barrier analysis

10. Despite the fact that techniques of modern biotechnology are viewed as a new and promising tool for crop improvement and novel uses of plants, animals, and microorganisms, there are concerns about the safety of some types of LMO to human health and the environment, in particular to wild and agricultural biodiversity. 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, as well as effect on the conventional agriculture. 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. 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.

11. Root causes of the threat arise from 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.

12. Main barriers for establishing effective national bisoafety system are lack of skilled personnel for biosafety in the country; lack of institutional capacity for biosafety; lack of more advanced technical equipment for detection of LMOs; and a lack of operative mechanisms for information change on certain aspects of LMO.

2.4. Institutional, sectoral and policy context

13. The inclusion of modern biotechnology in the overall national development policy has required 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 the CBD, the National Strategy and Action Plan for conservation of biodiversity was prepared and adopted in January 2004. In the 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 both modern biotechnology and biosafety, the Republic of Macedonia has signed the Cartagena Protocol on Biosafety in 2000, and ratified it on 14 June 2005.

14. 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 much of its legislation with the corresponding EU Directives

15. 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 officially authorised by the Ministry of Health in 2006.

16. 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 a Decision for establishing of the Scientific Committee for GMOs was approved 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 human and natural resources with the aim of reducing the

release of non-safe substances in the environment, there are no planned/defined measures or activities for implementation of this strategy in the context of LMOs.

2.5. Stakeholder mapping and analysis

- Ministry of Environment and Physical Planning, Agency of Environment
- Ministry of Agriculture, Forestry and Water Economy
    - Veterinary Directorate
    - Phytosanitary Directorate
    - Directorate for Seeds and Planting Material
- Ministry of Health, Food Directorate
- Ministry of Economy, Sector for Internal Market, Department for Consumer Protection
- Ministry of Finance, Customs Administration
- Faculty of Agricultural Sciences and Food, GMO laboratory
- Macedonian Academy of Arts and Sciences, Research Centre for Genetic Engineering and Biotechnology
- Consumers Organization of Macedonia
- Institute for Public Health, Sector for Hygiene and Environmental Protection
- Chambers and NGOs have primary role for effectiveness of public awareness and participation activities.
- The private sector is a major stakeholder group that will be affected by the implementation of the Protocol and the Law on GMO.

2.6. Baseline analysis and gaps

17. The political and legislative baseline on biosafety is provided by the NBF of Macedonia as well as in the Law on GMO (OG of RM 35/08). However effective implementation of the Law requires improving the understanding of administrators that take part in the decision-making process, official controls and inspections. For effective implementation of the Cartagena Protocol on Biosafety and the national Law, lawyers also required to be informed on biosafety issues.

18. The baseline for the effective system for handling requests, risk assessment, decision-making and risk management are the two functional laboratories for detection of GMOs, with the possible involvement of a third laboratory, plus the employees of relevant governmental institutions, scientific institutes and non-governmental institutions and organizations trained in the UNEP/GEF Project on Development of NBF, and also the BCH project. However, certain gaps remain in terms of lack of technical capacity and human resources to achieve a functional system. Institutional gaps exist for identification and detection of LMOs, implementation of standard methods and verification of results. This baseline will be further defined in the stocktaking activity at the beginning of the project

19. Recommendations for improving public awareness action plan as well as the publications disseminated in the scope of the UNEP/GEF Project on Development of the NBF provide the baseline for public awareness. However, the national BCH has only being established, but it is not yet operational due to technical and financial constraints.

2.7. Linkages with other GEF and non-GEF interventions

20. 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. 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.

21. 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 few other 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 infrastracture 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 in 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 implementaton 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.

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SECTION 3: INTERVENTION STRATEGY (ALTERNATIVE)

3.1. Project rationale, policy conformity and expected global environmental benefits

22. Project rationale is not only to finalise the NBF but to operationalise it as well. Policy conformity presents obligation under CBP, to the process of harmonization of the national legislation to the EU legislation and to any national policy mandate. By supporting the development and implementation of the National Biosafety Frameworks GEF contributes to the safe use of modern biotechnology in order to avoid potential negative impacts of specific LMOs on wild and agrobiodiversity, whilst allowing opportunities for improved environmental footprint of agriculture".

23. 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.

3.2. Project goal and objective

24. To build capacity to Macedonia for the development of a National Biosafety Framework for the safe use of modern biotechnology in line with international obligations, including the Cartagena

Protocol on Biosafety. The main objective is further elaborated in the Components section immediately below.

Project components and expected results

25. The project has 5 components as originally described in the GEF Project Identification Form (PIF) and shown below:

Project component	Expected outcomes	Expected outputs
COMPONENT 1 Stocktaking report	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 connencted to biosafety and prepared biosafety policy/ strategy
COMPONENT 2 Regulatory regime	Legislative system for risk assessment/ risk management, handling of LMO applications in place	[a] Biosafety regulations approved [b] Competent authorities (CA) and Scientific Advisory Committee (SAC) mandated
COMPONENT 3 Handling requests for authorization (including administrative processing for risk assessment and informed decision-making)	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	(a) Guidelines, methodologies and manuals on risk assessment and risk management prepared (b) Training on procedures for risk assessment and risk management (c) Internet portal functional for data collection, input and analysis for risk management and risk communication purposes. (d) National procedures required in order to use the Biosafety Clearing-House Mechanism and provide information to the Biosafety Clearing House in force
COMPONENT 4 Follow-up mechanisms (monitoring of environmental effects and enforcement: control and inspections)	Macedonia has public confidence in biosafety regulatory system enhanced due to effective monitoring and surveillance of intentional and non-intentional LMO presence and use	(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 response improved (c) Guidelines, methodologies and manuals on monitoring, inspections and emergency response prepared

		(d) Registration system with unique identifiers to trace back LMOs established
COMPONENT 5 Public participation and awareness	Macedonia has a functional system for public awareness and participation established for biosafety such that the level of public awareness on biosafety and participation in implementation of NBFis improved	(a) Public awareness action plan of NBF updated (b) National BCH strengthened (c) Increased raising public awareness through newsletters, videos, brochures, website and ensuring that the public are consulted for their views. Best practices and lessons learnt disseminated.

3.3. Intervention logic and key assumptions

26. The NBF implementation project will help Macedonia to set up a framework for management of LMOs at the national level, allowing meeting the requirements of the Cartagena Protocol. Following the global Development of NBF project it is widely recognized that further capacity building for biosafety in Macedonia is required to put in place a system for the safe use of modern biotechnology by means outlined in the project components (table above).

27. As the expected output of the first component is the stocktaking report, it is assumed that the governmental and non-governmental institutions will give attention to the project and actively participated to the stocktaking exercise.

28. Second Component of the project is the regulatory biosafety regime. Although the Law on GMO has entered into force in September 2008 its effective implementation depends on preparation of practical and understandable regulations, that the members of the National Biosafety Committee and the Commission on GMO have clear view on their responsibilities and issues related to biosafety, In addition its effective implementation depends of the legal and criminal liability, and the clear notification procedures for applicants. In this respect, as expected outputs of the second component of the project include approving the biosafey regulations and mandating competent authorities and scientific advisory committee and the Commission on GMO with providing their workplan and responsibilities. However it is assumed that during project duration there will be good cooperation between different sectors resulting in agreed legislation and administrative system.

29. Third component of the project is establishment of the system for handling of requests, risk assessment, decision-making and risk management of LMOs. The effectiveness of the system depends on good understanding of the members of the CA and SAC of the procedures of the handling of requests, risk assessment, decision-making and risk management of LMOs; the capacity and sustainability of technical staff to assess and manage risks that may arise from LMOs and effective information sharing. Therefore as expected outputs of the third component of the project are preparation of guidelines, methodologies and manuals on risk assessment and risk management, than providing training on procedures for risk assessment and risk management intended for responsible authorities, ensuring that the Internet portal is functional for data collection, input and analysis for risk management and risk communication purposes and defining national procedures required in order to use the Biosafety Clearing-House Mechanism and provide information to the Biosafety Clearing House in force

30. It is assumed that the institutional mechanisms and entities for administering biosafety, including competent national authorities and their responsibilities, willing to work and knowing their responsibilities relevant institutions collaborate effectively during and after the project. It is also assumed that the decision making system and administrative procedures, and Inter-agency communication and coordination adopted by government and accepted by public and stakeholders. As third assumption is that the Ministry is able to provide good internet connection to enable use of BCH and internet portal.

31. The fourth component of the project is establishment of the system for monitoring and inspection for LMOs. This component is critical to prevent unintentional and/or illegal introduction of LMOs. Effectiveness of the monitoring and inspection system depends on institutional capacity and human resources. To ensure sustainability of the human resources, training of trainers, training of key staff having role in inspections, border controls and judgment and providing manuals and guidelines have strategic importance. In order to achieve the third goal of the project, which is critical for effective implementation of NBF, the expected outputs of the forth component of the project are to purchase laboratory equipment and equipping reference laboratories for carrying out LMO detection and monitoring, establishing monitoring and inspection system for LMOs, improving human resources for monitoring, inspections, border controls, compliance to Law on GMO and the Protocol and emergency response. As other expected outputs are preparation of guidelines, methodologies and manuals on monitoring, inspections and emergency response as well as establishing the Registration system with unique identifiers to trace back LMOs. It is assumed that the process of accrediting reference laboratory and setting quality control will be finalized. Government and scientific institutions will provide sufficient money for maintaining the labs and equipment. Another assumption is that there will be 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 unintentional or illegal LMO movement.

33. Fifth component of the project is establishment of the public awareness and participation for biosafety. The effectiveness of this system will be ensured by updating the public awareness action plan of NBF, thus the level of public awareness on biosafety and participation into implementation of NBF will be improved, by strengthening the national BCH, increased raising public awareness through newsletters, videos, brochures, website and ensuring that the public are consulted for their views. Best practices and lessons learnt will be disseminated.

34. It is assumed that interest of the public to the biosafety issues will be maintained and even increased during and after the project execution. It is assumed also that relevant institutions collaborate effectively during and after the project.

3.4. Risk analysis and risk management measures

35. The main risk that could prevent the project from achieving its objectives within the 3 year expected duration is administrative and political delay. Delays are due to frequent change of governments in Macedonia which can be followed by the change of the key staff responsible for administration of the national biosafety system and may result in political disagreement which usually follows with delays, and even lack of approval of strategies and policies. For that purpose the activity A.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). With this purpose, it is important as a risk management measure to conduct well-planned and targeted awareness campaigns, involving all key stakeholders in different forms of meetings.

36. 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 B.1. (Organization of meetings of senior officials to prepare approval/enforcement of biosafety regulation) is foreseen to facilitate approval of the regulation.

37. In addition, advocacy at the highest possible level in the government is another aspect that this project will aim at. For that purpose, same as in the previous biosafety project the Steering Committe will be consisted of wide range of stakeholders, from scientists, decision-makers, donor organizations, farmer associations and opponent NGO's, providing a successful decision-making system and public awareness campaign 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 Acitivity 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 sustainablity of institutional colaboration and cooperation both during and after the project..

38. 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.

3.5. Consistency with national priorities or plans

39. The desire to apply modern 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. 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. In addition, as national priority is to strengthen the capacities of the state food inspectors for implementation of the process in accordance 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). For that purpose it is also necessary to establish the State Laboratory for 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), however, both the Scientific Committee and the Commission have still not realized working plan and their responsibilities are still not defined. 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.

3.6. Incremental cost reasoning

40. Within the context of the project, the baseline includes the activities carried out at domestic level ; 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 . The institutional baseline for handling of requests, risk assessment, risk management, monitoring and inspections constitutes laboratories with the potential to be included in the biosafety network and these laboratories also present 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. 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.. Monitoring and inspection system is the priority issue for Macedonia as being so rich of genetic origins and diversity for crops in the region. Mandatng 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.

3.7. Sustainability

41. As has been found with many other countries building capacity for biosafety, the development and operationalisation of a national biosafety framework cannot be achieved easily especially with a small project of short duration. This project is designed to start this process and to build capacity to point where a more comprehensive project can be put in place that will complete the design and integration of the national biosafety framework in such a way that it can become a part of the normal government operations, so that the activities connected to biosafety will be financed in the future from state budget and will not be depenedent on foreign financing and will not be project-based. Consequently, it will ensure ability for contribution to emerging biosafety standards and strengthen the cooperation in the Balkan region.

3.8. Replication

42. All project products will be available through the national BCH, therefore all other countries could benefit from the Macedonian national experience with Biosafety implementation. By involvement of international expertise, by providing support in all project components, the project will use experience from other countries.

3.9. Public awareness, communications and mainstreaming strategy

43. During the project on Development of NBF, participation of representatives from relevant governmental and non-governmental institutions and organizations was ensured through the National Co-ordinating Committee (NCC). Their involvement was also guaranteed in all stages of the project activities and minutes from NCC meetings were disseminated electronically via the BCH. Continuation of this strategy will be fulfilled in this project. In addition, since the national BCH will be operational early in project life, this project will ensure effective public awareness, communications and mainstreaming. This will be fulfilled by identifying and assigning of responsible body within the Ministry of Environment and Physical Planning that will serve as entity to promote public participation in decision-making in interactive manner by receiving public opinion. This body will also interact with the national BCH and update the feedback from the public in order to provide transparency. During this project it is planned to produce video, to publish brochure and posters intended for specific target groups (students on relevant universities, teachers in high schools, farmers and in coordination with the Chamber of commerce to produce leaflet intended for the private sector). In order to communicate the biosafety to the public it is also planned to participate in radio and TV programmes relevant for the topic, organize special workshops intended for informing the journalists on bioethics as well as to organize public debates.

3.10. Environmental and social safeguards

44. This project aims at capacity building in the area of biosafety. It is designed to support environmental protection with little direct activity in the field and will contribute to the safe use of modern biotechnology, preventing potential harm and giving the opportunity for both environmental and socio-economic benefits.

45. The project objective is to put in place a well-established and implemented NBF that will incorporate both science-based risk assessment and also socio-economic considerations, thus allowing Macedonia to make safe use of modern biotechnology as a part of its overall sustainable development programme. Taking into consideration that this project will support the protection of interest of different farmer groups, such as organic production, conventional farmers on one side but as well farmers that support GM crops, there are socio-economic impacts. By improving the laboratories for LMO detection, this project will also improve the monitoring and surveillance system in the country. There is long-term effect of the project as biotechnology is an evolving area and by defining clear rules initially, the country will benefit from it later on, and evading the harm to the environment and human health.

SECTION 4: INSTITUTIONAL FRAMEWORK AND IMPLEMENTATION ARRANGEMENTS

46. GEF Implementing Agency is UNEP, Executing Agency is the Agency of Environment within the Ministry of Environment and Physical Planning of the Government of Republic of Macedonia.

47. The project will be executed by the Ministry of Environment and Physical Planning's Agency of Environment, and project funds will be transferred through a government account specifically allocated for this project. The project will be guided and monitored through a National Coordination Committee (NCC) and managed by the National Project Coordinator, who will be assigned by the

National Executing Agency (NEA), in consultation with UNEP. As members of the NCC, Ministry of Agriculture, Forestry and Water Economy, Ministry of Health and Custom Directorate will participate in defining specific training need and nominate adequate participants in public debates. NGOs and Chamber of Commerce, as members of NCC, will provide support with their participation in project workshops and in the process of raising public awareness and participation.

SECTION 5: STAKEHOLDER PARTICIPATION

48. Major roles in the project implementation will have the following institutions:

INSTITUTION	PARTICIPATION
Ministry of Environment and physical planning	Main role in the project implementation: Executing Agency , responsible for general project coordination
Ministry of Agriculture, Forestry and Water Economy	Involved in determination of necessary training for agriculture inspectors, participation in public debates
Ministry of Health	Involved in determination of necessary training of food inspectors, laboratories for GMO detection, participation in public debates
Ministry of Economy, Ministry of Finance through the Custom Directorate	Members of NCC, involved in determination of necessary training of custom officers
NGOs representing the public and consumer rights as well as NGOs working on conservation and sustainable use of biodiversity	Members of NCC, their participation will also be encouraged in workshops during the project and timely dissemination of information will be provided on the national BCH
Chamber of Commerce and the private sector	Members of NCC, their participation will also be encouraged in workshops during the project and timely dissemination of information will be provided on the national BCH
Research institutions and laboratories: (Macedonian Academy of Sciences and Art, Faculty for agricultural sciences and food)	Will be part of setting monitoring and surveillance system in Macedonia

SECTION 6: MONITORING AND EVALUATION PLAN

49. The project will follow UNEP standard monitoring, reporting and evaluation processes and procedures. Substantive and financial project reporting requirements are summarized in Appendix 7. Reporting requirements and templates are an integral part of the UNEP legal instrument to be signed by the NEA and UNEP.

50. 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.

51. The M&E plan will be reviewed and revised as necessary during the project inception workshop to ensure project stakeholders understand their roles and responsibilities vis-à-vis project monitoring and evaluation. Indicators and their means of verification may also be fine-tuned at the inception workshop. Day-to-day project monitoring is the responsibility of the project management team but other project partners will have responsibilities to collect specific information to track the indicators. It is the responsibility of the Project Manager to inform UNEP of any delays or difficulties faced during implementation so that the appropriate support or corrective measures can be adopted in a timely fashion.

52. The project Steering Committee will receive periodic reports on progress and will make recommendations to UNEP concerning the need to revise any aspects of the Results Framework or the M&E plan. Project oversight to ensure that the project meets UNEP and GEF policies and procedures is the responsibility to the Task Manager in UNEP-GEF. The Task Manager will also review the quality of draft project outputs, provide feedback to the project partners, and establish peer review procedures to ensure adequate quality of scientific and technical outputs and publications.

53. At the time of project approval 50 percent of baseline data is available. Baseline data gaps will be addressed during the first year of project implementation. A plan for collecting the necessary baseline data is presented in Appendix 7. The main aspects for which additional information are needed are exact status of modern biotechnology and biosafety capacity across public and private sectors.

54. Project supervision will take an adaptive management approach. The Task Manager will develop a project supervision plan at the inception of the project which will be communicated to the project partners during the inception workshop. The emphasis of the Task Manager supervision will be on outcome monitoring but without neglecting project financial management and implementation monitoring. Progress vis-à-vis delivering the agreed project global environmental benefits will be assessed with the Steering Committee at agreed intervals. Project risks and assumptions will be regularly monitored both by project partners and UNEP. Risk assessment and rating is an integral part of the Project Implementation Review (PIR). The quality of project monitoring and evaluation will also be reviewed and rated as part of the PIR. Key financial parameters will be monitored quarterly to ensure cost-effective use of financial resources.

55. A mid-term management review or evaluation will take place on June 2012 as indicated in the project milestones. The review will include all parameters recommended by the GEF Evaluation Office for terminal evaluations and will verify information gathered through the GEF tracking tools, as relevant. The review will be carried out using a participatory approach whereby parties that may benefit or be affected by the project will be consulted. Such parties were identified during the stakeholder analysis (see Section 5 of the project document). The project Steering Committee will participate in the mid-term review and develop a management response to the evaluation recommendations along with an implementation plan. It is the responsibility of the UNEP Task Manager to monitor whether the agreed recommendations are being implemented.

56. An independent terminal evaluation will take place at the end of project implementation. The Evaluation and Oversight Unit (EOU) of UNEP will manage the terminal evaluation process. A review of the quality of the evaluation report will be done by EOU and submitted along with the report to the GEF Evaluation Office not later than 6 months after the completion of the evaluation. The

standard terms of reference for the terminal evaluation are included in Appendix 9. These will be adjusted to the special needs of the project.

57. The GEF tracking tools are attached as Appendix 15. These will be updated at mid-term and at the end of the project and will be made available to the GEF Secretariat along with the project PIR report. As mentioned above the mid-term and terminal evaluation will verify the information of the tracking tool.

SECTION 7: PROJECT FINANCING AND BUDGET

7.1. Overall project budget

GEF financing: 407,000 USD

Co-financing: 236,000 USD

Total: 643,000 USD

7.2. Project co-financing

Co-financing (in-kind): 236,000 USD

7.3. Project cost-effectiveness

58. In general, 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 levels of 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. 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 sustainablity 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.

APPENDICES

Appendix 1: Budget by project components and UNEP budget lines

Appendix 2: Co-financing by source and UNEP budget lines

Appendix 3: Incremental cost analysis

Appendix 4: Results Framework

Appendix 5: Workplan and timetable

Appendix 6: Key deliverables and benchmarks

Appendix 7: Costed M&E plan

Appendix 8: Summary of reporting requirements and responsibilities

Appendix 9: Standard Terminal Evaluation TOR

Appendix 10: Decision-making flowchart and organizational chart

Appendix 11: Terms of Reference

Appendix 12: Co-financing commitment letters from project partners

Appendix 13: Endorsement letters of GEF National Focal Points

Appendix 14: Draft procurement plan

Appendix 15: Tracking Tools

Project No: GFL-2328-2716-[XXXX]
Project Name: Support for the Implementation of the draft National Biosafety Framework of Republic of Macedonia
Executing Agency: Ministry of Environment and Physical Planning / Agency of Environment

UNEP BUDGET LINE/OBJECT OF EXPENDITURE		ACTIVITY (AS PER ANNEX 1B)							EXPENDITURE BY YEAR (AS PER ANNEX 2B)					
		A	B	C	D	E	F	Total	Y 1 (2009)	Y2 (2010)	Y3 (2011)	Y4 (2012)	Y5 (2013)	Total
		US$	US$	US$	US$	US$	US$	US$	US$	US$	US$	US$	US$	US$
10 PROJECT PERSONNEL COMPONENT														
1102	Project Staff	0.00	0.00	0.00	0.00	0.00	34,000.00	**$34,000.00**	11,000.00	11,000.00	12,000.00	0.00	0.00	**34,000.00**
1120	Administrative Staff	0.00	0.00	0.00	0.00	0.00	0.00	**$0.00**	0.00	0.00	0.00	0.00	0.00	**0.00**
1201	International Consultants	2,000.00	8,000.00	59,000.00	13,000.00	19,300.00	0.00	**$101,300.00**	2,000.00	57,150.00	42,150.00	0.00	0.00	**101,300.00**
1202	National Consultants	5,400.00	0.00	3,500.00	1,000.00	1,000.00	0.00	**$10,900.00**	4,300.00	1,800.00	4,800.00	0.00	0.00	**10,900.00**
1601	Staff Travel & Transport	50.00	0.00	200.00	0.00	0.00	0.00	**$250.00**	250.00	0.00	0.00	0.00	0.00	**250.00**
1999	**Component Total**	7,450.00	8,000.00	62,700.00	14,000.00	20,300.00	34,000.00	**$146,450.00**	17,550.00	69,950.00	58,950.00	0.00	0.00	**146,450.00**
20 SUB-CONTRACT COMPONENT														
2201	Sub-contract to governmental agencies	0.00	0.00	0.00	0.00	0.00	0.00	**$0.00**	0.00	0.00	0.00	0.00	0.00	**0.00**
2301	Sub-contract to private firms	0.00	12,100.00	0.00	5,000.00	57,200.00	0.00	**$74,300.00**	5,000.00	15,500.00	53,800.00	0.00	0.00	**74,300.00**
2999	**Component Total**	0.00	12,100.00	0.00	5,000.00	57,200.00	0.00	**$74,300.00**	5,000.00	15,500.00	53,800.00	0.00	0.00	**74,300.00**
30 TRAINING COMPONENT														
3201	Training	0.00	6,600.00	23,650.00	12,800.00	7,500.00	0.00	**$50,550.00**	0.00	27,175.00	23,375.00	0.00	0.00	**50,550.00**
3301	Meetings	1,800.00	2,000.00	2,500.00	0.00	2,000.00	0.00	**$8,300.00**	2,800.00	1,000.00	4,500.00	0.00	0.00	**8,300.00**
3999	**Component Total**	1,800.00	8,600.00	26,150.00	12,800.00	9,500.00	0.00	**$58,850.00**	2,800.00	28,175.00	27,875.00	0.00	0.00	**58,850.00**
40 EQUIPMENT & PREMISES COMPONENT														
4101	Office supplies and consummables	100.00	300.00	600.00	200.00	2,000.00	0.00	**$3,200.00**	1,100.00	1,250.00	850.00	0.00	0.00	**3,200.00**
4102	Laboratory supplies and consummables	0.00	0.00	0.00	10,000.00	0.00	0.00	**$10,000.00**	0.00	10,000.00	0.00	0.00	0.00	**10,000.00**
4201	Non Laboratory Purchase	0.00	0.00	0.00	3,300.00	0.00	6,700.00	**$10,000.00**	6,700.00	3,300.00	0.00	0.00	0.00	**10,000.00**
4202	Laboratory Equipment	0.00	0.00	0.00	80,000.00	0.00	0.00	**$80,000.00**	0.00	80,000.00	0.00	0.00	0.00	**80,000.00**
4301	Office Premises	0.00	0.00	0.00	0.00	0.00	0.00	**$0.00**	0.00	0.00	0.00	0.00	0.00	**0.00**
4302	Research Facilities	0.00	0.00	0.00	0.00	0.00	0.00	**$0.00**	0.00	0.00	0.00	0.00	0.00	**0.00**
4999	**Component Total**	100.00	300.00	600.00	93,500.00	2,000.00	6,700.00	**$103,200.00**	7,800.00	94,550.00	850.00	0.00	0.00	**103,200.00**
50 MISCELLANEOUS COMPONENT														
5101	Equipment Maintenance	0.00	0.00	0.00	0.00	0.00	0.00	**$0.00**	0.00	0.00	0.00	0.00	0.00	**0.00**
5201	Publication, Translation, Dissemination and reporting costs	0.00	1,000.00	2,200.00	0.00	0.00	0.00	**$3,200.00**	0.00	3,200.00	0.00	0.00	0.00	**3,200.00**
5202	Audit Reports	0.00	0.00	0.00	0.00	0.00	6,000.00	**$6,000.00**	2,000.00	2,000.00	2,000.00	0.00	0.00	**6,000.00**
5301	Communications (tel, fax, e-mail, etc..)	0.00	0.00	0.00	0.00	0.00	0.00	**$0.00**	0.00	0.00	0.00	0.00	0.00	**0.00**
5302	Others	0.00	0.00	0.00	0.00	0.00	0.00	**$0.00**	0.00	0.00	0.00	0.00	0.00	**0.00**
5303	Monitoring & Evaluation	0.00	0.00	0.00	0.00	0.00	15,000.00	**$15,000.00**	2,000.00	8,000.00	5,000.00	0.00	0.00	**15,000.00**
5375	UNDP charges	0.00	0.00	0.00	0.00	0.00	0.00	**$0.00**	0.00	0.00	0.00	0.00	0.00	**0.00**
5999	**Component Total**	0.00	1,000.00	2,200.00	0.00	0.00	21,000.00	**$24,200.00**	4,000.00	13,200.00	7,000.00	0.00	0.00	**24,200.00**
TOTAL COSTS		**9,350.00**	**30,000.00**	**91,650.00**	**125,300.00**	**89,000.00**	**61,700.00**	**$407,000.00**	**37,150.00**	**221,375.00**	**148,475.00**	**0.00**	**0.00**	**$407,000.00**

A: Biosafety Policy
B: Regulatory regime
C: Handling requests for authorization (including administrative processing for risk assessment and informed decision-making)
D: Follow-up mechanisms (monitoring of environmental effects and enforcement: control and inspections)
E: Public awareness and participation
F: Project Coordination

Activity Code		Project Activities / SubActivities	Year 1		Year 2		Year 3		Year 4		Year 5		Total	
			GEF	GOV	GEF	GOV	GEF	GOV	GEF	GOV	GEF	GOV	GEF	GOV
A		**Biosafety Policy**												
A	1	Preparation meetings with stakeholders for introduction to the gap analysis on the stocktaking report	350.00	600.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**350.00**	**600.00**
A	2	Prepare biosafety policy / strategy in line with other national policies and development plans, amending existing policies (food safety etc)	2,300.00	0.00	2,300.00	0.00	2,300.00	0.00	0.00	0.00	0.00	0.00	**6,900.00**	**0.00**
A	3	Gap analysis on the national technological capacity at public and private level, its effect on implementation of national biosafety frameworks, and means to improve it.	2,100.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**2,100.00**	**0.00**
A	4	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
A	5	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
A	6	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
A	7	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
A	8	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
A	9	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
A	10	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
A	11	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
A	12	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
A	13	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
A	14	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
A	15	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
		Total A	**4,750.00**	**600.00**	**2,300.00**	**0.00**	**2,300.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	9,350.00	600.00
B		**Regulatory regime**												
B	1	Review/finalisation draft biosafety laws (or regulations and secondary legal acts)	5,000.00	2,000.00	5,000.00	2,000.00	2,100.00	2,000.00	0.00	0.00	0.00	0.00	**12,100.00**	**6,000.00**
B	2	Training workshops/seminars on CP and how to meet minimum requirements, international obligations of the country, regulatory instruments related to biosafety in the country	0.00	0.00	6,050.00	300.00	0.00	0.00	0.00	0.00	0.00	0.00	**6,050.00**	**300.00**
B	3	Set up an internal task force composed of representatives of different government departments on regulatory issues	100.00	3,000.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**100.00**	**3,000.00**
B	4	Develop appropriate rules for enforcement of performing risk assessment and management for implementing the LMOs Act	0.00	0.00	4,100.00	1,000.00	0.00	0.00	0.00	0.00	0.00	0.00	**4,100.00**	**1,000.00**
B	5	Develop plan of work/procedures on the CAs and SAC	2,100.00	1,000.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**2,100.00**	**1,000.00**
B	6	Two days workshop for 30 representatives of governmental institutions, organizations and NGOs, on: “Biosafety issues and the regulations for the implementation of the Law on GMO”. The workshop will focus on biosafety issues of regulating and controlling the contained use and the deliberate release of LMOs	0.00	0.00	4,000.00	300.00	1,550.00	300.00	0.00	0.00	0.00	0.00	**5,550.00**	**600.00**
B	7	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
B	8	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
B	9	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
B	10	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
B	11	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
B	12	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
B	13	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
B	14	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
B	15	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
		Total B	**7,200.00**	**6,000.00**	**19,150.00**	**3,600.00**	**3,650.00**	**2,300.00**	**0.00**	**0.00**	**0.00**	**0.00**	30,000.00	11900

Activity Code		Project Activities / SubActivities	Year 1		Year 2		Year 3		Year 4		Year 5		Total	
			GEF	GOV	GEF	GOV	GEF	GOV	GEF	GOV	GEF	GOV	GEF	GOV
C		**Handling requests for authorization (including administrative processing for risk assessment and informed decision-making)**												
C	1	(Definition) drafting of RA national guidelines and procedures,	0.00	0.00	8,900.00	3,200.00	0.00	0.00	0.00	0.00	0.00	0.00	**8,900.00**	**3,200.00**
C	2	Development of a "check list" for RA practitioners.	0.00	0.00	0.00	0.00	4,100.00	4,500.00	0.00	0.00	0.00	0.00	**4,100.00**	**4,500.00**
C	3	Identification, appointment and revision of RA experts and entity	2,000.00	3,500.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**2,000.00**	**3,500.00**
C	4	Trainings on risk assessment and risk management: • LMOs risk assessment and risk management, • LMOs testing and monitoring, • Legal issues, • Administrative Procedures and • The control over the transboundary movement of LMO	0.00	0.00	21,200.00	3,300.00	21,200.00	5,300.00	0.00	0.00	0.00	0.00	**42,400.00**	**8,600.00**
C	5	Training workshop: "Transboundary movement of LMO and the Cartagena Protocol o Biosafety"	0.00	0.00	12,625.00	2,950.00	12,625.00	4,450.00	0.00	0.00	0.00	0.00	**25,250.00**	**7,400.00**
C	6	Training workshop: "Biosafety of biotechnology research, trials and applications" - Safety requirements and procedures for LMOs contained use, deliberate release and commercial use	0.00	0.00	0.00	0.00	9,000.00	5,200.00	0.00	0.00	0.00	0.00	**9,000.00**	**5,200.00**
C	7	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
C	8	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
C	9	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
C	10	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
C	11	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
C	12	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
C	13	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
C	14	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
C	15	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
		Total C	**2,000.00**	**3,500.00**	**42,725.00**	**9,450.00**	**46,925.00**	**19,450.00**	**0.00**	**0.00**	**0.00**	**0.00**	**91,650.00**	**32400**
D		**Follow-up mechanisms (monitoring of environmental effects and enforcement: control and inspections)**												
D	1	Develop guidelines and rules for monitoring (in cooperation with other countries)	0.00	0.00	5,000.00	2,000.00	0.00	0.00	0.00	0.00	0.00	0.00	**5,000.00**	**2,000.00**
D	2	Legal training for responsible agencies (decision-makers, government officers, etc) o the implementation of biosafety procedures, included handling of applications and the development of guidelines and regulations.	0.00	0.00	6,000.00	1,500.00	6,000.00	1,500.00	0.00	0.00	0.00	0.00	**12,000.00**	**3,000.00**
D	3	Assessment and evaluation of existing facilities	1,000.00	4,200.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**1,000.00**	**4,200.00**
D	4	Improving Laboratory for LMO at the Faculty of Agricultural Sciences and Food and the Research Institution for Genetic Engeneering at the Macedonian Academy of Sciences and Art, to enable the centres to perform inspections on LMOs and related products, and carry out training activities	0.00	0.00	93,300.00	6,500.00	0.00	0.00	0.00	0.00	0.00	0.00	**93,300.00**	**6,500.00**
D	5	Setting up a national information database of registers, dossiers, trial data, deliberate release, commercial use, import and export, and any other information required under the Cartagena Protocol on Biosafety with an adequate mechanism for information sharing/networking and security management	0.00	0.00	5,000.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**5,000.00**	**0.00**
D	6	Training for experts from laboratories on LMO monitoring and inspection procedures	0.00	0.00	9,000.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**9,000.00**	**0.00**
D	7	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
D	8	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
D	9	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
D	10	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
D	11	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
D	12	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
D	13	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
D	14	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
D	15	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
		Total D	**1,000.00**	**4,200.00**	**118,300.00**	**10,000.00**	**6,000.00**	**1,500.00**	**0.00**	**0.00**	**0.00**	**0.00**	**125,300.00**	**15700**

Activity Code		Project Activities / SubActivities	Year 1		Year 2		Year 3		Year 4		Year 5		Total	
			GEF	GOV	GEF	GOV	GEF	GOV	GEF	GOV	GEF	GOV	GEF	GOV
E		**Public awareness and participation**												
E	1	Identifying responsible office for managing public awareness and education campaign relating to Biosafety in scope of government agency and setting its rules of work	500.00	4,000.00	500.00	3,000.00	500.00	3,000.00	0.00	0.00	0.00	0.00	**1,500.00**	**10,000.00**
E	2	Surveys for public opinion, incl ecological, economic, and sociological survey, including indigenous knowledge	0.00	0.00	0.00	0.00	5,000.00	400.00	0.00	0.00	0.00	0.00	**5,000.00**	**400.00**
E	3	Public debates - panel discussions/group roundtables for government officials and representatives of NGOs and Civil Society (Women's Groups, Municipalities Based Organisations and farmers) representatives for developing awareness strategies and information training programmes at grass root level.	0.00	0.00	5,000.00	0.00	5,000.00	0.00	0.00	0.00	0.00	0.00	**10,000.00**	**0.00**
E	4	Develop curricula for Biosafety in relation to the conservation and sustainable use of biodiversity, taking also into account risks to human health	0.00	0.00	3,000.00	500.00	0.00	0.00	0.00	0.00	0.00	0.00	**3,000.00**	**500.00**
E	5	Training for educators, i.e. officers in charge of public awareness, training, education on how to promote direct target groups on using of modern biotechnology products to ensure safety, public hearings, and public consultative meetings for Biosafety law sensitisation and procedures of release of LMOs for government/private sectors representatives	0.00	0.00	9,400.00	100.00	9,900.00	100.00	0.00	0.00	0.00	0.00	**19,300.00**	**200.00**
E	6	Courses in educational institutions, public talks	0.00	0.00	0.00	0.00	5,000.00	0.00	0.00	0.00	0.00	0.00	**5,000.00**	**0.00**
E	7	Develop TV and radio educational programmes in collaboration with the Education and Higher Education authorities on biosafety issues	0.00	0.00	0.00	0.00	31,000.00	0.00	0.00	0.00	0.00	0.00	**31,000.00**	**0.00**
E	8	Develop and distribute biosafety awareness materials - including posters, flyers and leaflets - and a manual on biosafety processes and procedures, in different indigenous languages	0.00	0.00	0.00	0.00	14,200.00	0.00	0.00	0.00	0.00	0.00	**14,200.00**	**0.00**
E	9	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
E	10	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
E	11	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
E	12	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
E	13	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
E	14	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
E	15	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
		Total E	**500.00**	**4,000.00**	**17,900.00**	**3,600.00**	**70,600.00**	**3,500.00**	**0.00**	**0.00**	**0.00**	**0.00**	**89,000.00**	**11100**
F		**Project Coordination**												
F	1	National Project Coordinator	11,000.00	0.00	11,000.00	0.00	12,000.00	0.00	0.00	0.00	0.00	0.00	**34,000.00**	**0.00**
F	2	Project technical staff - one administration and one financial	0.00	36,966.00	0.00	36,968.00	0.00	36,966.00	0.00	0.00	0.00	0.00	**0.00**	**110,900.00**
F	3	Two desktop and two laptop computers, multifunctional machine (copier, scanner, fax and printer), color printer	6,700.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**6,700.00**	**0.00**
F	4	#REF!	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
F	5	M&E	4,000.00	6,500.00	10,000.00	6,500.00	7,000.00	7,000.00	0.00	0.00	0.00	0.00	**21,000.00**	**20,000.00**
F	6	Project management	0.00	11,166.00	0.00	11,100.00	0.00	11,134.00	0.00	0.00	0.00	0.00	**0.00**	**33,400.00**
F	7	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
F	8	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
F	9	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
F	10	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
F	11	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
F	12	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
F	13	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
F	14	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
F	15	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**	**0.00**
		Total F	**21,700.00**	**54,632.00**	**21,000.00**	**54,568.00**	**19,000.00**	**55,100.00**	**0.00**	**0.00**	**0.00**	**0.00**	**61,700.00**	**164300**
		Grand Total	**37,150.00**	**72,932.00**	**221,375.00**	**81,218.00**	**148,475.00**	**81,850.00**	**0.00**	**0.00**	**0.00**	**0.00**	**407,000.00**	**236,000.00**

Appendix 3: Incremental Cost Analysis:

Within the context of this project, the baseline includes the activities carried out at the domestic level with respect to each specific project component; the increment includes the activities proposed under this project proposal for the purpose of meeting obligations under the Cartagena Protocol and Macedonia's international obligations to be financed through GEF contribution and National Co-financing.

Project Component	*Baseline*	*Alternative*	*Increment*	*Incremental Cost*
Component 1: Assessment of the status of modern biotechnology and biosafety and national capacity needs assessment and preparation of biosafety strategy	a) Some information is contained in draft NBF, but no comprehensive information available 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	a) By early 2011, stocktaking report is finalized 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	a) Some information is contained in draft NBF, but no comprehensive information available 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	- Cost to GEF Budget "Global benefit": **US$ 9,350** - Co-finance "Government contribution": **US$ 6,000**
		US$ 9.350		
Component 2: Legislative system for risk assessment/ risk management, handling of LMO applications in place	a) Primary act was adopted in 2008, but it is lacking secondary legislation. b) Ministry of Environment nominated and CA for GMOs. SAC, but they are lacking the work plan	a) By 2011, analysis of needs for secondary legal acts. By 2012 drafting legal acts. By 2013 adopting. b)By 2011, CAs and SAC have their workplan	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. b) Names and coordinates of CA and SAC are	- Cost to GEF Budget "Global benefit": **US$ 30,000** - Co-finance from the Government: **US$ 15,000**

			available in project website and BCH.	
	US$	**US$ 30,000**		
Component 3:				
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	a) No manuals available in local language. b) Personnel are not trained in regard of RA/RM. c) No internet portal available	a) By 2013, manuals drafted and published. b) By 2013, 11 trainings performed to train relevant personnel. c) By 2012, internet portal functional.	a) - Guidelines available - Internal manuals available in project website - Summary available on the BCH - Printed Publications, Manuals available, copies sent by NPC - Media coverage of biosafety legislation summary of media coverage included into periodic reporting c) - Information documents available in local languages in project website, copies sent by NPC	- Cost to GEF Budget "Global benefit": **US$ 91,350** - Co-finance from the Government: **US$ 60,000**
Component 4:				
Macedonia has public confidence in biosafety regulatory system enhanced due to effective monitoring and surveillance of intentional and non-intentional LMO presence and use	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,	a) By 2013, national referent laboratory/ies fully equipped b)By 2013, three trainings organized for monitoring staff	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,	- Cost to GEF Budget "Global benefit": **US$ 125,600** - Co-finance from the Government: **US$ 30,000**

	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 c)No technical guidelines available d) NO registration system	c)By 2013, technical guidelines published d) By 2013, registration system established and functional	manuals etc to regular reporting. Training manuals and technical documents for monitoring and inspection available in project website, copies sent by NPC c)Address of registration system sent by NPC d) Monitoring and inspection plans available in national websites of relevant authorities.	
<u>Component 5:</u> Macedonia has a functional system for public awareness and participation established for biosafety	a) Public awareness plan and campaign strategy was drafted in 2003-2005, but need updating b) General public awareness	a) By 2012, awareness plan and campaign strategy updated By 2013, public awareness improved b) By 2013 trained staff from Office for public relation on biosafety c) By 2013.	a)Action plan and strategy available in project website Access records of the national BCH. b)Instructional and user manuals available in project website and copies	- Cost to GEF Budget "Global benefit": **US$ 89,000** - Co-finance from the Government: **US$ 20,000**

	of biosafety and participation currently are on very low level Lack of institution responsible for public relations on biosafety c) Currently, only general information available on national BCH d) Lack of consultation with public for views on biosafety.	d) By 2013 developed media coverage by preparation of written and video material on biosafety	National BCH functional c)Country information available on the BCH central portal d)Feedbacks and suggestions from workshop participants are recorded and available in project website List of workshop participants and agenda sent by NPC	sent by NPC
Monitoring and evaluation			**US$ 41,000**	- Cost to GEF Budget "Global benefit": **US$ 21,000** - Co-finance from the Government: **US$ 20,000**
Project management			**US 40,700**	- Cost to GEF Budget "Global benefit": **US$ 40,700** - Co-finance from the Government: **US$ 85,000**
Total				- Cost to GEF Budget "Global benefit": **US$ 407,000** - Co-finance from the Government: **US$ 236,000**

Annex A: Project Results Framework

Objectives and Outcomes/Outputs	Objectively Verifiable Indicators	Baseline	Indicators	Means of Verification	Important Assumptions
Objective: Implementation of the National Biosafety Framework in line with national priorities and obligations to the Cartagena Protocol on Biosafety.	By the end of the project, Macedonia has in place biosafety policy, legislative framework and administrative framework for implementing CPB.	Draft NBF was prepared during 2003 - 2005	By 2013 updated NBF in place and adopted by the government	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.	Government supports the NBF, stability in policy and government, no delays in project implementation, especially in regards to the legal component
Outcome A: Assessment of the status of modern biotechnology and biosafety and national capacity needs assessment and preparation of biosafety strategy					
Outputs: **(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.	(a) Stocktaking report is produced, containing an assessment of current resources, infrastructure, legislation in place, as well as analysis of existing gaps.	a) Some information is contained in draft NBF, but no comprehensive information available	a) By early 2011, stocktaking report is finalized	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).	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.
(b) Amended national policies connected to biosafety and prepared biosafety policy/ strategy	(b) Biosafety policy drafted/ agreed/adopted, other policies amended	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	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	(b) NPC to include draft policy on biosafety and amended policy papers to project website	b) Good cooperation between other sectors connected to biosafety.
Outcome B Legislative system for risk assessment/ risk management, handling of LMO applications in place					
Outputs: (a) Biosafety	a) Secondary legislation	a) Primary act was adopted in	a) By 2011, analysis of	a) The corresponding	a) Good cooperation between

regulations approved	prepared, amended and discussed with stakeholders representatives and approved	2008, but it is lacking secondary legislation.	needs for secondary legal acts. By 2012 drafting legal acts. By 2013 adopted.	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.	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					
Outputs: a).Guidelines, methodologies and manuals on risk assessment and risk management prepared	a) Creation of technical guidelines for handling of requests (including Risk Assessment/Risk Management guidelines)	a) No manuals available in local language.	a) By 2013, manuals drafted and published.	a) Guidelines available Internal manuals available in project website Summary available on the BCH Printed Publications, Manuals available, copies sent by NPC	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. .
b).Training on procedures for risk assessment and risk management	b) Training for risk assessment and risk management for personnel from CAs and scientific institutions organized	b) Personnel are not trained in regard of RA/RM.	b) By 2013, 11 training events performed to train relevant personnel.	b) Training reports sent by NPC	
c).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	c) Maintenance of functional national biosafety portal - BCH for collection of data, input and analysis for risk management and risk communication purposes Preparation of national procedures required in order to use the BCH mechanism and provide	c) No internet portal available	c) By 2012, internet portal functional.	c) Information documents available in local languages in project website, copies sent by NPC National BCH connected to main portal of BCH	c) Ministry is able to provide good internet conncetion to enable use of BCH and internet portal.

Mechanism and provide information to the Biosafety Clearing House in force	information to the BCH				
Outcome D: Macedonia has public confidence in biosafety regulatory system enhanced due to effective monitoring and surveillance of intentional and non-intentional LMO presence and use					
Outputs a) Laboratory equipment purchased and reference laboratories equipped to carry out LMO detection and monitoring	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.	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.	a) By 2013, national referent laboratory/ies fully equipped	a) NPC to include the list of needed equipment to the regular reporting, as well as list of purchased equipment	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) 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	b) Organization of national and international training workshops for immediate stakeholders on monitoring, producing training reports Relevant staff of responsible agencies are trained on monitoring and evaluation and have	b) No staff trained for monitoring and evaluation	b) By 2013, three trainings organized for monitoring staff	b) NPC to include workshop reports, manuals etc to regular reporting.	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 unintentional or illegal LMO movement. -

	been issued respective certification				
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	c) By 2013, technical guidelines published	c) Training manuals and 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.	
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	d) By 2013, registration system established and functional	d) Address of registration system sent by NPC	
Outcome E: Macedonia has a functional system for public awareness and participation established for biosafety					
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 - d) Public will better understand biosafety and participate actively in campaigns and other activities, no opposition from their side.
b) Level of public awareness on biosafety and participation into implementation of NBF improved	b) Number Of nationals accessing the nBCH.	b) General public awareness of biosafety and participation currently are on very low level Lack of institution responsible for public relations on biosafety	b) By 2013, public awareness improved By 2013 trained staff from Office for public relation on biosafety	b)Instructional and user manuals available in project website and copies sent by NPC	No interest group will be working against the project activities. Government will cooperate in the sustaining the awareness activities and taking it over after the end of the project.
c. National BCH strengthened	c) Number of records on the nBCH.	c) Currently, only general information available on national BCH	c) By 2013. National BCH functional	c)Country information available on the BCH central portal	-
d. Increased raising	d) Number of people	d) Lack of consultation with	d) By 2013 developed	d) Feedbacks and suggestions	

public awareness through newsletters, videos, brochures, website and ensuring that the public are consulted for their views. Best practices and lessons learnt disseminated.	trained to continue tasks; workshop reports	public for views on biosafety.	media coverage by preparation of written and video material on biosafety	from workshop participants are recorded and available in project website List of workshop participants and agenda sent by NPC	

Project workplan

Component	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Component A: Stocktaking report												
Proposed activities												
1. Preparation meetings with stakeholders for introduction to the gap analysis on the stocktaking report												
2. Prepare biosafety policy / strategy in line with other national policies and development plans, amending existing policies (food safety etc)												
3. Gap analysis on the national technological capacity at public and private level, its effect on implementation of national biosafety frameworks, and means to improve it.												
Component B - Regulatory regime												
Proposed activities												
1. Review/finalisation draft biosafety laws (or regulations and secondary legal acts)												
2. Training workshops/seminars on CP and how to meet minimum requirements, international obligations of the country, regulatory instruments related to biosafety in the country												

3. Set up an internal task force composed of representatives of different government departments on regulatory issues												
4. Develop appropriate rules for enforcement of performing risk assessment and management for implementing the LMOs Act												
5. Develop plan of work/procedures on the CAs and SAC												
6. Two days workshop for 30 representatives of governmental institutions, organizations and NGOs, on: “Biosafety issues and the regulations for the implementation of the Law on GMO”. The workshop will focus on biosafety issues of regulating and controlling the contained use and the deliberate release of LMOs												
Component C Handling requests for authorization (including administrative processing for risk assessment and informed decision-making)												
Proposed activities												
1. (Definition) drafting of RA national guidelines and procedures, "												
2. Development of a “check list” for RA practitioners.												
3. Identification, appointment and revision of RA experts and entity												
4. Trainings on risk assessment and risk management: a) LMOs risk assessment and risk management, b) LMOs testing and monitoring, c) Legal issues, d) Administrative Procedures and e) The control over the transboundary movement of LMO												
5. Training workshop: “Transboundary movement of LMO and the Cartagena Protocol on Biosafety”												

6. Training workshop: “Biosafety of biotechnology research, trials and applications” - Safety requirements and procedures for LMOs contained use, deliberate release and commercial use												
Component D - Follow-up mechanisms (monitoring of environmental effects and enforcement: control and inspections)												
Proposed activities												
1. Develop guidelines and rules for monitoring (in cooperation with other countries)												
2. Legal training for responsible agencies (decision-makers, government officers, etc) on the implementation of biosafety procedures, included handling of applications and the development of guidelines and regulations.												
3. Assessment and evaluation of existing facilities												
4. Improving Laboratory for LMO at the Faculty of Agricultural Sciences and Food and the Research Institution for Genetic Engineering at the Macedonian Academy of Sciences and Art, to enable the centers to perform inspections on LMOs and related products, and carry out training activities												
5. Setting up a national information database of registers, dossiers, trial data, deliberate release, commercial use, import and export, and any other information required under the Cartagena Protocol on Biosafety with an adequate mechanism for information sharing/networking and security management												
6. Training for experts from laboratories on LMO monitoring and inspection procedures												
Component E - Public awareness and participation												
Proposed activities												
1. Identifying responsible office for managing public awareness and education campaigns relating to Biosafety in scope of government agency and setting its rules of work												
2. Surveys for public opinion, incl ecological, economic, and sociological survey, including												

indigenous knowledge												
3. Public debates - panel discussions/group roundtables for government officials and representatives of NGOs and Civil Society (Women's Groups, Municipalities Based Organisations and farmers) representatives for developing awareness strategies and information training programmes at grass root level.												
4. Develop curricula for Biosafety in relation to the conservation and sustainable use of biodiversity, taking also into account risks to human health												
5. Training for educators, i.e. officers in charge of public awareness, training, education on how to promote direct target groups on using of modern biotechnology products to ensure safety, public hearings, and public consultative meetings for Biosafety law sensitisation and procedures of release of LMOs for government/private sectors representatives												
6. Courses in educational institutions, public talks												
7. Develop TV and radio educational programmes in collaboration with the Education and Higher Education authorities on biosafety issues												
8. Develop and distribute biosafety awareness materials - including posters, flyers and leaflets - and a manual on biosafety processes and procedures, in different indigenous languages												
Component F – Project coordination												
Proposed activities												
1. Monitoring & Evaluation												
2. Project management												

Appendix 6: Key Deliverables and Benchmark

Key Deliverables (Outputs)	Benchmark
Component 1: Stocktaking on biosafety in Macedonia	
Outcome 1.1. Assessment of the status of modern biotechnology and biosafety and national capacity needs assessment and preparation of biosafety strategy	
Outputs: ▪ (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. ▪ (b) Amended national policies connected to biosafety and prepared biosafety policy/ strategy	▪ a) By early 2011, stocktaking report is finalized ▪ 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
Component 2: Regulatory regime	
Outcome 2.1. Legislative system for risk assessment/ risk management, handling of LMO applications in place	
Outputs: ▪ [a] Biosafety regulations approved ▪ [b] Competent authorities (CA) and Scientific Advisory Committee (SAC) mandated	▪ a) By 2011, analysis of needs for secondary legal acts. By 2012 drafting legal acts. By 2013 adopting. ▪ b) By 2011, CAs and SAC have their workplan
Component 3: Handling requests for authorization (including administrative processing for risk assessment and informed decision-making)	
Outcome 3.1. 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	
Outputs: ▪ (a) Guidelines, methodologies and manuals on risk assessment and risk management prepared ▪ (b).Training on procedures for risk assessment and risk management ▪ (c).Internet portal functional for data collection, input and analysis for risk management and risk communication purposes ▪ (d) National procedures required in order to use the Biosafety Clearing-House Mechanism and provide information to the Biosafety Clearing House in force	▪ a) By 2013, manuals drafted and published. ▪ b) By 2013, 11 trainings performed to train relevant personnel. ▪ c) By 2012, internet portal functional.
Component 4: Follow-up mechanisms (monitoring of environmental effects and enforcement: control and inspections)	
Outcome 4.1. Macedonia has public confidence in biosafety regulatory system enhanced due to effective monitoring and surveillance of intentional and non-intentional LMO presence and use	
Outputs: ▪ 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 response improved ▪ c) Guidelines, methodologies and manuals on monitoring, inspections and emergency response prepared	▪ a) By 2012, awareness plan and campaign strategy updated ▪ By 2013, public awareness improved ▪ b) By 2013 trained staff from Office for public relation on biosafety ▪ c) By 2013. National BCH functional ▪ d) By 2013 developed media coverage by preparation of written and video material on biosafety

▪ d) Registration system with unique identifiers to trace back LMOs established ▪	
Component 5: Public participation	
Outcome 5.1. Macedonia has a functional system for public awareness and participation established for biosafety	
Outputs: ▪ a. Public awareness action plan of NBF updated ▪ b. Level of public awareness on biosafety and participation into implementation of NBF improved ▪ c. National BCH strengthened d. Increased raising public awareness through newsletters, videos, brochures, website and ensuring that the public are consulted for their views. Best practices and lessons learnt disseminated.	a) By 2012, awareness plan and campaign strategy updated By 2013, public awareness improved b) By 2013 trained staff from Office for public relation on biosafety c) By 2013. National BCH functional d) By 2013 developed media coverage by preparation of written and video material on biosafety

Results-Based Monitoring and Evaluation Framework

Appendix 7 - Costed M&E Work Plan Summary

Objective / Outcome [1]	Outcome / objective level indicator[2]	Baseline Conditions[3]	Mid point Target[4] (as relevant)	End of Project Target	Means of Verification[5]	Monitoring / sampling (frequency / size) [6]	Location / Group	Responsibility	Time frame [7]	Budget (Object of expenditure & cost)[8]
COMPONENT 1: Stocktaking on biosafety in Macedonia										
Assessment of the status of modern biotechnology and biosafety and national capacity needs assessment and preparation of	(a) Stocktaking report is produced, containing an assessment of current resources, infrastructure, legislation in	a) Some information is contained in draft NBF, but no comprehensive information available b) Some	a) By early 2011, stocktaking report is finalized b) By 2011 all relevant policies are analyzed by	- The implementation of Cartagena Protocol on Biosafety is supported by the consolidation of a unified governmentally	a) All components of the National Biosafety Framework are reviewed and are elaborated into the project work-plan,	annual	- NCAs including MOE - Steering Committee -Key stakeholder personnel -Events participants	- MOE (as NEA) - NPC - Consultants	Annually in October	Included in the project design

1 All project outcomes should be included in this column. The objective here is to provide the means to monitor progress in achieving the results set for the life of the project. Goals and long term impact indicators should not be included in this section, but may be discussed in other sections of the project document and M&E plan.

2 Only key indicators should be included (not more than 2 or 3 per outcome). Appropriate selection of outcome indicators is essential to assess progress in achieving project results.

3 Please note that if no baseline information for a particular indicator exists it is difficult to justify the targets. Also, please note that baseline data should be collected during the project preparation phase (PPG). If essential baseline data is not complete at the time of Work Program entry (for FSP) or CEO approval (for MSPs) the end of the first year of project implementation is the deadline for collecting the necessary data. The plan for the collection of such baseline data should be added in the next section along with its associated cost.

4 The mid point target will be reviewed at the Mid-Term Review along with validation of other focal area Tracking Tools. It is acknowledged that mid-point targets may not be relevant to all projects or all project outcomes. Flexibility will be applied.

5 The means of verification is the source of data that the project team will use to track the indicator (e.g., if the indicator is "forest cover diversity", the means of verification could be "field surveys data" and "satellite imagery). Reviewing of project reports alone is insufficient.

6 This column should describe for each indicator the size (e.g., whether entire protected area or only a fraction, or, for example, in the case of a survey, how many people would be covered). The frequency (e.g., once in the lifetime of the project, quarterly during the first year, yearly, etc.)

7 Expected date (month/year) in which the monitoring activity will take place

8 For example, 15 satellite images @ $1,000 each = $15,000, or 4 field sampling trips by 2 staff @ $300 each= $1,200

biosafety strategy	place, as well as analysis of existing gaps. (b) Biosafety policy drafted/ agreed/adopted, other policies amended	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	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	approved Biosafety policy, strategy and action plan. - Roles and responsibilities of all involved governmental institutions with regards to Biosafety clearly identified	incorporating the findings of the stocktaking assessment. NPC to include stocktaking report to the periodic reporting (ANUBIS). (b) NPC to include draft policy on biosafety and amended policy papers to project website					
COMPONENT 2: Regulatory regime										
Legislative system for risk assessment/ risk management, handling of LMO applications in place	a) Secondary legislation prepared, amended and discussed with stakeholders representatives and approved b) A multi-sect oral working group is set up to provide assistance and guidance to the development of the regulatory regime	a) Primary act was adopted in 2008, but it is lacking secondary legislation. b) Ministry of Environment nominated and CA for GMOs. SAC, but they are lacking the work plan	a) By 2011, analysis of needs for secondary legal acts. By 2012 drafting legal acts. By 2013 adopting. b)By 2011, CAs and SAC have their workplan	[a] Biosafety regulations approved [b] Competent authorities (CA) and Scientific Advisory Committee (SAC) mandated	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. b) Names and coordinates of CA and SAC are available in project website and BCH.	annual	- NCAs - Steering Committee - MOE -Key stakeholder personnel -Events participants	- MOE (as NEA) - NPC - Consultants	Annually in October	Included in the project design
COMPONENT 3: Handling requests for authorization (including administrative processing for risk assessment and informed decision-making).										

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	a) Creation of technical guidelines for handling of requests (including Risk Assessment/Risk Management guidelines) b) Maintenance of functional national biosafety portal - BCH for collection of data, input and analysis for risk management and risk communication purposes Preparation of national procedures required in order to use the BCH mechanism and provide information to the BCH	a) No manuals available in local language. b) Personnel are not trained in regard of RA/RM. c) No internet portal available	a) By 2013, manuals drafted and published. b) By 2013, 11 trainings performed to train relevant personnel. c) By 2012, internet portal functional.	a).Guidelines, methodologies and manuals on risk assessment and risk management prepared b).Training on procedures for risk assessment and risk management c).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	a) -Guidelines available - - Internal manuals available in project website - - Summary available on the BCH - - Printed Publications, - - Manuals available, - - copies sent by NPC - - Media coverage	annual	- NCAs - Steering Committee - Scientific subcommittees - MOE -Key stakeholder personnel -Events participants	- MOE (as NEA) - NPC - Consultants	Annually in October	Included in the project design

					of biosafety legislation summary of media coverage included into periodic reporting c) Information documents available in local languages in project website, copies sent by NPC Information documents available in local languages in project website, copies sent by NPC					
COMPONENT 4: Follow-up mechanisms (monitoring of environmental effects and enforcement: control and inspections)										
Macedonia has public confidence in biosafety regulatory system enhanced due to effective monitoring and	a. detailed outline of the laboratory equipment necessary for complementing the existing laboratory at the	a) Republic of Macedonia has only one laboratory for testing and identification of GMOs in food. In 2006, the	a)By 2013, national referent laboratory/ies fully equipped b)By 2013,	a)Laboratory equipment purchased and reference laboratories equipped to carry out LMO detection and	a)NPC to include the list of needed equipment to the regular reporting, as well as list of purchased	annual	- NCAs - Steering Committee - MOE -Key stakeholder personnel	- MOE (as NEA) - NPC - Consultants	Annually in October	Included in the project design

surveillance of intentional and non-intentional LMO presence and use	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 of responsible agencies are trained on monitoring and evaluation and have been issued respective certification c. Technical guidelines for monitoring developed and distributed to responsible personnel d Establishment of registration system with unique	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	three trainings organized for monitoring staff c)By 2013, technical guidelines published d) By 2013, registration system established and functional	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 response improved c)Guidelines, methodologies and manuals on monitoring, inspections and emergency response prepared d) Registration system with unique identifiers to trace back LMOs established	equipment b) NPC to include workshop reports, manuals etc to regular reporting. Training manuals and technical documents for monitoring and inspection available in project website, copies sent by NPC c)Address of registration system sent by NPC d) Monitoring and inspection plans available in national websites of relevant authorities.		-Events participants			

	identifiers to trace back LMOs established. Monitoring and inspection are included in work plan and strategies of relevant enforcement agencies	evaluation c)No technical guidelines available d) NO registration system								
COMPONENT 5: Public participation										
Macedonia has a functional system for public awareness and participation established for biosafety	a)Public awareness action plan and public service campaign strategy b) Number Of nationals accessing the nBCH. c) Number of records on the nBCH. d)Number of people trained to continue tasks; workshop reports	a)Public awareness plan and campaign strategy was drafted in 2003-2005, but need updating b)General public awareness of biosafety and participation currently are on very low level Lack of institution responsible for public relations on biosafety c)Currently, only general information available on national BCH d) Lack of consultation with public for	a) a)By 2012, awareness plan and campaign strategy updated By 2013, public awareness improved b) b)By 2013 trained staff from Office for public relation on biosafety c) c) By 2013.	a. Public awareness action plan of NBF updated b. Level of public awareness on biosafety and participation into implementation of NBF improved c. National BCH strengthened d. Increased raising public awareness through newsletters, videos, brochures, website and ensuring that the public are consulted for	a)Action plan and strategy available in project website Access records of the national BCH. b)Instructional and user manuals available in project website and copies sent by NPC c)Country information available on the BCH central portal d)Feedbacks and suggestions from workshop participants are recorded and available in	annual	- NCAs - Steering Committee - MOE -Key stakeholder personnel -Events participants	- MOE (as NEA) - NPC - Consultants	Annually in October	Included in the project design

		views on biosafety.	National BCH functional d) d)By 2013 developed media coverage by preparation of written and video material on biosafety	their views. Best practices and lessons learnt disseminated.	project website List of workshop participants and agenda sent by NPC					

1. Monitoring Framework and Budget [9]
2. Cost of acquisition of essential baseline data during first year of project[10]:
   The baseline data was already collected as a part of the project preparation activities.
3. Cost of project inception workshop (please include proposed location, number of participants):
   To be carried out in Skopje, with 30 participants. The workshop is an activity under component 2 of the project. The GEF cost of the inception workshop is expected to be US $ 6,050.
4. Cost of Mid-Term Review/Evaluation:
   The midterm review is a desk review and is estimated to cost US $ 5,000
5. Cost of Terminal Evaluation:
   The terminal evaluation is estimated to cost US$5,000
6. Any additional M&E costs [11]:

[9] Detailed monitoring plan should be included in the M&E project section. This table is primarily intended to reflect how the outcome level indicators will be tracked to facilitate monitoring of **results** (as opposed to monitoring of project implementation progress). The implementation of the Results-based Monitoring Framework will be assessed at mid point and at end of project (through the Mid-Term review and Terminal Evaluation processes). The quality of M&E implementation will be rated with the Project Implementation Review (PIR). The contents of this table should be validated and agreed upon at the project inception meeting.

[10] Refer to detailed M&E work plan for additional information on what data will be collected and what activities will be undertaken. The data to be collected needs to be consistent with the indicators included in the table above.

[11] Please describe the activity and included the expected cost. Additional M&E costs could be related to the following: (i) Additional reviews and evaluation processes for phased and tranched projects; (ii) application & validation of tracking tools.

Total annual Audit Budget is expected to be US$6,000 as GEF contribution.

Total costs (this figure should be included in the consolidated project budget and in the request for CEO endorsement/approval in the M&E budget line):

The total cost for M&E is estimated to as US $35,000 and has been included in the consolidated project budget. This figure include a GEF contribution of US $15,000 and a government contribution (in-kind) of US$ 20,000 for monitoring and reporting of the project

Appendix 8 – **Reporting requirements**	**Due date**	**Format to be appended to UNEP legal instrument as**	**Responsibility of**
Procurement plan (goods and services)	2 weeks before project inception meeting	N/A	National Project Coordinator
Inception Report	1 month after project inception meeting	N/A	National Project Coordinator
Expenditure report accompanied by explanatory notes	Quarterly on or before 30 April, 31 July, 31 October, 31 January	Annex 11	National Project Coordinator
Cash Advance request and details of anticipated disbursements	Quarterly or when required	Annex 7B	National Project Coordinator
Progress report	Half-yearly on or before 31 January	Annex 8	National Project Coordinator
Audited report for expenditures for year ending 31 December	Yearly on or before 30 June	N/A	Executing partner to contract firm
Inventory of non-expendable equipment	Yearly on or before 31 January	Annex 6	National Project Coordinator
Co-financing report	Yearly on or before 31 July	Annex 12	National Project Coordinator
Project implementation review (PIR) report	Yearly on or before 31 August	Annex 9	Project Manager, TM, DGEF FMO
Minutes of steering committee meetings	Yearly (or as relevant)	N/A	National Project Coordinator
Mission reports and “aide memoire” for executing agency	Within 2 weeks of return	N/A	TM, DGEF FMO
Final report	2 months of project completion date	Annex 10	National Project Coordinator
Final inventory of non-expendable equipment		Annex 9	National Project Coordinator
Equipment transfer letter		Annex 10	National Project Coordinator
Final expenditure statement	3 months of project completion date	Annex 11	National Project Coordinator
Mid-term review or Mid-term evaluation	Midway though project	N/A	TM or EOU (as relevant)
Final audited report for expenditures of project	6 months of project completion date	N/A	Executing partner to contract firm
Independent terminal evaluation report	6 months of project completion date	Appendix 9 to Annex 1 of CEO-ER	EOU

APPENDIX 9 - STANDARD TERMINAL EVALUATION TERMS OF REFERENCE

Terminal Evaluation of the UNEP GEF project "Support for Implementation of the National Biosafety Framework for Republic of Macedonia"

1. PROJECT BACKGROUND AND OVERVIEW

Project rationale

The objective was stated as: The Overall Goal of the project is that by 2014 Republic of Macedonia has a workable and transparent national biosafety framework, in line with its national development priorities and international obligations.

The indicators given in the project document for this stated objective were:

As listed in Results Framework (appendix 4) to the project document.

Relevance to GEF Programmes

The project is in line with: GEF IV Strategic Programme 6 (BD-SP6) - Biosafety

Executing Arrangements

The implementing agency(ies) for this project is UNEP and the national executing agency is the Ministry of Environment and Physical Planning, Republic of Macedonia.

Project Activities

The project comprised activities grouped in 5 components in the addition to the project management and Monitoring and evaluation.

Budget

At project inception the following budget prepared:

	GEF	Co-funding
Project preparation funds:	$	
GEF Medium Size Grant	$407,000	$236,000
TOTAL (including project preparation funds)	**$407,000**	**$236,000**

Co-funding sources: Government in-kind

Anticipated:

APPENDIX 9
TERMS OF REFERENCE FOR THE EVALUATION

1. Objective and Scope of the Evaluation

The objective of this terminal evaluation is to examine the extent and magnitude of any project impacts to date and determine the likelihood of future impacts. The evaluation will also assess project performance and the implementation of planned project activities and planned outputs against actual results. The evaluation will focus on the following main questions:

1. Did the project help to build awareness among key target audiences (international conventions and initiatives, national level policy-makers, regional and local policy-makers, resource managers and practitioners).
2. Did the outputs of the project articulate options and recommendations for mainstreaming of biosafety into the national policies/plans? Were these options and recommendations used? If so by whom?
3. To what extent did the project outputs produced have the weight of scientific authority and credibility necessary to influence policy makers and other key audiences?

Methods

This terminal evaluation will be conducted as an in-depth evaluation using a participatory approach whereby the UNEP/DGEF Task Manager, key representatives of the executing agencies and other relevant staff are kept informed and consulted throughout the evaluation. The consultant will liaise with the UNEP/EOU and the UNEP/DGEF Task Manager on any logistic and/or methodological issues to properly conduct the review in as independent a way as possible, given the circumstances and resources offered. The draft report will be circulated to UNEP/DGEF Task Manager, key representatives of the executing agencies and the UNEP/EOU. Any comments or responses to the draft report will be sent to UNEP / EOU for collation and the consultant will be advised of any necessary or suggested revisions.

The findings of the evaluation will be based on the following:

1. A desk review of project documents including, but not limited to:
   (a) The project documents, outputs, monitoring reports (such as progress and financial reports to UNEP and GEF annual Project Implementation Review reports) and relevant correspondence.
   (b) Notes from the Steering Group meetings.
   (c) Other project-related material produced by the project staff or partners.
   (d) Relevant material published on the project web-site: www.biosafety.gov.mk

2. Interviews with project management and technical support including members of the National Coordination Committee

3. Interviews and Telephone interviews with intended users for the project outputs and other stakeholders involved with this project, including in the participating countries and international bodies. The Consultant shall determine whether to seek additional information and opinions from representatives of donor agencies and other organizations. As appropriate, these interviews could be combined with an email questionnaire.

4. Interviews with the UNEP/DGEF project task manager and Fund Management Officer, and other relevant staff in UNEP dealing with Biodiversity (Biosafety) -related activities as necessary. The Consultant shall also gain broader perspectives from discussions with relevant GEF Secretariat staff.

5. Field visits[1] to project staff

Key Evaluation principles.
In attempting to evaluate any outcomes and impacts that the project may have achieved, evaluators should remember that the project's performance should be assessed by considering the difference between the answers to two simple questions ***"what happened?***" and ***"what would have happened anyway?"***. These questions imply that there should be consideration of the baseline conditions and trends in relation to the intended project outcomes and impacts. In addition it implies that there should be plausible evidence to **attribute** such outcomes and impacts **to the actions of the project**.

Sometimes, adequate information on baseline conditions and trends is lacking. In such cases this should be clearly highlighted by the evaluator, along with any simplifying assumptions that were taken to enable the evaluator to make informed judgements about project performance.

2. Project Ratings

The success of project implementation will be rated on a scale from 'highly unsatisfactory' to 'highly satisfactory'. In particular the evaluation shall **assess and rate** the project with respect to the eleven categories defined below:[2]

A. Attainment of objectives and planned results:

The evaluation should assess the extent to which the project's major relevant objectives were effectively and efficiently achieved or are expected to be achieved and their relevance.

- *Effectiveness:* Evaluate how, and to what extent, the stated project objectives have been met, taking into account the "achievement indicators". The analysis of outcomes achieved should include, *inter alia*, an assessment of the extent to which the project has directly or indirectly assisted policy and decision-makers to apply information supplied by biodiversity indicators in their national planning and decision-making. In particular:
  - Evaluate the immediate impact of the project on Biodiversity (Biosafety) monitoring and in national planning and decision-making and international understanding and use of biodiversity indicators.
  - As far as possible, also assess the potential longer-term impacts considering that the evaluation is taking place upon completion of the project and that longer term impact is expected to be seen in a few years time. Frame recommendations to enhance future project impact in this context. Which will be the major 'channels' for longer term impact from the project at the national and international scales?

[1] Evaluators should make a brief courtesy call to GEF Country Focal points during field visits if at all possible.

[2] However, the views and comments expressed by the evaluator need not be restricted to these items.

- *Relevance*: In retrospect, were the project's outcomes consistent with the focal areas/operational program strategies? Ascertain the nature and significance of the contribution of the project outcomes to the Cartagena Protocol on Biosafety and the Convention on Biological Diversity and the wider portfolio of the GEF.
- *Efficiency*: Was the project cost effective? Was the project the least cost option? Was the project implementation delayed and if it was, then did that affect cost-effectiveness? Assess the contribution of cash and in-kind co-financing to project implementation and to what extent the project leveraged additional resources. Did the project build on earlier initiatives, did it make effective use of available scientific and / or technical information. Wherever possible, the evaluator should also compare the cost-time vs. outcomes relationship of the project with that of other similar projects.

B. Sustainability:

Sustainability is understood as the probability of continued long-term project-derived outcomes and impacts after the GEF project funding ends. The evaluation will identify and assess the key conditions or factors that are likely to contribute or undermine the persistence of benefits after the project ends. Some of these factors might be outcomes of the project, e.g. stronger institutional capacities or better informed decision-making. Other factors will include contextual circumstances or developments that are not outcomes of the project but that are relevant to the sustainability of outcomes. The evaluation should ascertain to what extent follow-up work has been initiated and how project outcomes will be sustained and enhanced over time.

Five aspects of sustainability should be addressed: financial, socio-political, institutional frameworks and governance, environmental (if applicable). The following questions provide guidance on the assessment of these aspects:

- *Financial resources.* Are there any financial risks that may jeopardize sustenance of project outcomes? What is the likelihood that financial and economic resources will not be available once the GEF assistance ends (resources can be from multiple sources, such as the public and private sectors, income generating activities, and trends that may indicate that it is likely that in future there will be adequate financial resources for sustaining project's outcomes)? To what extent are the outcomes of the project dependent on continued financial support?
- *Socio-political:* Are there any social or political risks that may jeopardize sustenance of project outcomes? What is the risk that the level of stakeholder ownership will be insufficient to allow for the project outcomes to be sustained? Do the various key stakeholders see that it is in their interest that the project benefits continue to flow? Is there sufficient public / stakeholder awareness in support of the long term objectives of the project?
- *Institutional framework and governance.* To what extent is the sustenance of the outcomes of the project dependent on issues relating to institutional frameworks and governance? What is the likelihood that institutional and technical achievements, legal frameworks, policies and governance structures and processes will allow for, the project outcomes/benefits to be sustained? While responding to these questions consider if the required systems for accountability and transparency and the required technical know-how are in place.

- *Environmental.* Are there any environmental risks that can undermine the future flow of project environmental benefits? The TE should assess whether certain activities in the project area will pose a threat to the sustainability of the project outcomes. For example; construction of dam in a protected area could inundate a sizable area and thereby neutralize the biodiversity-related gains made by the project; or, a newly established pulp mill might jeopardise the viability of nearby protected forest areas by increasing logging pressures; or a vector control intervention may be made less effective by changes in climate and consequent alterations to the incidence and distribution of malarial mosquitoes.

C. Achievement of outputs and activities:

- Delivered outputs: Assessment of the project's success in producing each of the programmed outputs, both in quantity and quality as well as usefulness and timeliness.
- Assess the soundness and effectiveness of the methodologies used for developing the technical documents and related management options in the participating countries
- Assess to what extent the project outputs produced have the weight of scientific authority / credibility, necessary to influence policy and decision-makers, particularly at the national level.

D. Catalytic Role

Replication and catalysis. What examples are there of replication and catalytic outcomes? Replication approach, in the context of GEF projects, is defined as lessons and experiences coming out of the project that are replicated or scaled up in the design and implementation of other projects. Replication can have two aspects, replication proper (lessons and experiences are replicated in different geographic area) or scaling up (lessons and experiences are replicated within the same geographic area but funded by other sources). Specifically:

- Do the recommendations for management of {project} coming from the country studies have the potential for application in other countries and locations?

If no effects are identified, the evaluation will describe the catalytic or replication actions that the project carried out.

E. Assessment monitoring and evaluation systems.

The evaluation shall include an assessment of the quality, application and effectiveness of project monitoring and evaluation plans and tools, including an assessment of risk management based on the assumptions and risks identified in the project document. The Terminal Evaluation will assess whether the project met the minimum requirements for 'project design of M&E' and 'the application of the Project M&E plan' (see minimum requirements 1&2 in *Annex 4* to this Appendix). GEF projects must budget adequately for execution of the M&E plan, and provide adequate resources during implementation of the M&E plan. Project managers are also expected to use the information generated by the M&E system during project implementation to adapt and improve the project.

M&E during project implementation

- *M&E design.* Projects should have sound M&E plans to monitor results and track progress towards achieving project objectives. An M&E plan should include a baseline (including data, methodology, etc.), SMART indicators (see

Annex 4) and data analysis systems, and evaluation studies at specific times to assess results. The time frame for various M&E activities and standards for outputs should have been specified.

- *M&E plan implementation.* A Terminal Evaluation should verify that: an M&E system was in place and facilitated timely tracking of results and progress towards projects objectives throughout the project implementation period (perhaps through use of a logframe or similar); annual project reports and Progress Implementation Review (PIR) reports were complete, accurate and with well justified ratings; that the information provided by the M&E system was used during the project to improve project performance and to adapt to changing needs; and that projects had an M&E system in place with proper training for parties responsible for M&E activities.
- *Budgeting and Funding for M&E activities.* The terminal evaluation should determine whether support for M&E was budgeted adequately and was funded in a timely fashion during implementation.

F. Preparation and Readiness

Were the project's objectives and components clear, practicable and feasible within its timeframe? Were the capacities of executing institution and counterparts properly considered when the project was designed? Were lessons from other relevant projects properly incorporated in the project design? Were the partnership arrangements properly identified and the roles and responsibilities negotiated prior to project implementation? Were counterpart resources (funding, staff, and facilities), enabling legislation, and adequate project management arrangements in place?

G. Country ownership / driveness:

This is the relevance of the project to national development and environmental agendas, recipient country commitment, and regional and international agreements. The evaluation will:

- Assess the level of country ownership. Specifically, the evaluator should assess whether the project was effective in providing and communicating biodiversity information that catalyzed action in participating countries to improve decisions relating to the conservation and management of the focal ecosystem in each country.
- Assess the level of country commitment to the generation and use of biodiversity indicators for decision-making during and after the project, including in regional and international fora.

H. Stakeholder participation / public awareness:

This consists of three related and often overlapping processes: information dissemination, consultation, and "stakeholder" participation. Stakeholders are the individuals, groups, institutions, or other bodies that have an interest or stake in the outcome of the GEF-financed project. The term also applies to those potentially adversely affected by a project. The evaluation will specifically:

- Assess the mechanisms put in place by the project for identification and engagement of stakeholders in each participating country and establish, in consultation with the stakeholders, whether this mechanism was successful, and identify its strengths and weaknesses.
- Assess the degree and effectiveness of collaboration/interactions between the various project partners and institutions during the course of implementation of the project.

- Assess the degree and effectiveness of any various public awareness activities that were undertaken during the course of implementation of the project.

I. Financial Planning

Evaluation of financial planning requires assessment of the quality and effectiveness of financial planning and control of financial resources throughout the project's lifetime. Evaluation includes actual project costs by activities compared to budget (variances), financial management (including disbursement issues), and co- financing. The evaluation should:

- Assess the strength and utility of financial controls, including reporting, and planning to allow the project management to make informed decisions regarding the budget and allow for a proper and timely flow of funds for the payment of satisfactory project deliverables.
- Present the major findings from the financial audit if one has been conducted.
- Identify and verify the sources of co- financing as well as leveraged and associated financing (in co-operation with the IA and EA).
- Assess whether the project has applied appropriate standards of due diligence in the management of funds and financial audits.
- The evaluation should also include a breakdown of final actual costs and co-financing for the project prepared in consultation with the relevant UNEP/DGEF Fund Management Officer of the project (table attached in *Annex 1* to this Appendix Co-financing and leveraged resources).

J. Implementation approach:

This includes an analysis of the project's management framework, adaptation to changing conditions (adaptive management), partnerships in implementation arrangements, changes in project design, and overall project management. The evaluation will:

- Ascertain to what extent the project implementation mechanisms outlined in the project document have been closely followed. In particular, assess the role of the various committees established and whether the project document was clear and realistic to enable effective and efficient implementation, whether the project was executed according to the plan and how well the management was able to adapt to changes during the life of the project to enable the implementation of the project.
- Evaluate the effectiveness and efficiency and adaptability of project management and the supervision of project activities / project execution arrangements at all levels (1) policy decisions: Steering Group; (2) day to day project management in each of the country executing agencies and the Ministry of Environment, Forest and Tourism.

K. UNEP Supervision and Backstopping

- Assess the effectiveness of supervision and administrative and financial support provided by UNEP/DGEF.
- Identify administrative, operational and/or technical problems and constraints that influenced the effective implementation of the project.

The ***ratings will be presented in the form of a table***. Each of the eleven categories should be rated separately with **brief justifications** based on the findings of the main analysis. An

overall rating for the project should also be given. The following rating system is to be applied:

HS = Highly Satisfactory
S = Satisfactory
MS = Moderately Satisfactory
MU = Moderately Unsatisfactory
U = Unsatisfactory
HU = Highly Unsatisfactory

3. Evaluation report format and review procedures

The report should be brief, to the point and easy to understand. It must explain; the purpose of the evaluation, exactly what was evaluated and the methods used. The report must highlight any methodological limitations, identify key concerns and present evidence-based findings, consequent conclusions, recommendations and lessons. The report should be presented in a way that makes the information accessible and comprehensible and include an executive summary that encapsulates the essence of the information contained in the report to facilitate dissemination and distillation of lessons.

The evaluation will rate the overall implementation success of the project and provide individual ratings of the eleven implementation aspects as described in Section 1 of this TOR. *The ratings will be presented in the format of a table* **with brief justifications based on the findings of the main analysis.**

Evidence, findings, conclusions and recommendations should be presented in a complete and balanced manner. Any dissident views in response to evaluation findings will be appended in an annex. The evaluation report shall be written in English, be of no more than 50 pages (excluding annexes), use numbered paragraphs and include:

i) An **executive summary** (no more than 3 pages) providing a brief overview of the main conclusions and recommendations of the evaluation;
ii) **Introduction and background** giving a brief overview of the evaluated project, for example, the objective and status of activities; The GEF Monitoring and Evaluation Policy, 2006, requires that a TE report will provide summary information on when the evaluation took place; places visited; who was involved; the key questions; and, the methodology.
iii) **Scope, objective and methods** presenting the evaluation's purpose, the evaluation criteria used and questions to be addressed;
iv) **Project Performance and Impact** providing *factual evidence* relevant to the questions asked by the evaluator and interpretations of such evidence. This is the main substantive section of the report. The evaluator should provide a commentary and analysis on all eleven evaluation aspects (A − K above).
v) **Conclusions and rating** of project implementation success giving the evaluator's concluding assessments and ratings of the project against given evaluation criteria and standards of performance. The conclusions should provide answers to questions about whether the project is considered good or bad, and whether the results are considered positive or negative. The ratings

should be provided with a brief narrative comment in a table (see *Annex 1* to this Appendix);

vi) **Lessons (to be) learned** presenting general conclusions from the standpoint of the design and implementation of the project, based on good practices and successes or problems and mistakes. Lessons should have the potential for wider application and use. All lessons should 'stand alone' and should:
- Briefly describe the context from which they are derived
- State or imply some prescriptive action;
- Specify the contexts in which they may be applied (if possible, who when and where)

vii) **Recommendations** suggesting *actionable* proposals for improvement of the current project. In general, Terminal Evaluations are likely to have very few (perhaps two or three) actionable recommendations.

Prior to each recommendation, the issue(s) or problem(s) to be addressed by the recommendation should be clearly stated.

A high quality recommendation is an actionable proposal that is:
1. Feasible to implement within the timeframe and resources available
2. Commensurate with the available capacities of project team and partners
3. Specific in terms of who would do what and when
4. Contains results-based language (i.e. a measurable performance target)
5. Includes a trade-off analysis, when its implementation may require utilizing significant resources that would otherwise be used for other project purposes.

viii) **Annexes** may include additional material deemed relevant by the evaluator but must include:
1. The Evaluation Terms of Reference,
2. A list of interviewees, and evaluation timeline
3. A list of documents reviewed / consulted
4. Summary co-finance information and a statement of project expenditure by activity
5. The expertise of the evaluation team.

TE reports will also include any response / comments from the project management team and/or the country focal point regarding the evaluation findings or conclusions as an annex to the report, however, such will be appended to the report by UNEP EOU.

Examples of UNEP GEF Terminal Evaluation Reports are available at www.unep.org/eou

Review of the Draft Evaluation Report

Draft reports submitted to UNEP EOU are shared with the corresponding Programme or Project Officer and his or her supervisor for initial review and consultation. The DGEF staff and senior Executing Agency staff are allowed to comment on the draft evaluation report. They may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions. The consultation also seeks feedback on the proposed recommendations. UNEP EOU collates all review comments and provides them to the evaluators for their consideration in preparing the final version of the report.

4. Submission of Final Terminal Evaluation Reports.

The final report shall be submitted in electronic form in MS Word format and should be sent to the following persons:

Segbedzi Norgbey, Chief,
UNEP Evaluation and Oversight Unit
P.O. Box 30552-00100
Nairobi, Kenya
Tel.: + (254-20)762-4181
Fax: + (254-20)762-3158
Email: Segbedzi.Norgbey@unep.org

With a copy to:

Maryam Niamir-Fuller,
Director
UNEP/Division of GEF Coordination
P.O. Box 30552-00100
Nairobi, Kenya
Tel: + (254-20)762-4166
Fax: + (254-20)762-4041/2
Email: Maryam.Niamir-Fuller@unep.org

The Final evaluation will also be copied to the following GEF National Focal Points.

Mrs. Daniela Renders
Head of Unit for Bilateral and Multilateral Cooperation
Ministry of Environment and Physical Planning
Goce Delcev bb,
Skopje 1000
Macedonia
Tel/Fax. +389 2 3215 373
Email.danielastefkova@yahoo.com

The final evaluation report will be published on the Evaluation and Oversight Unit's web-site www.unep.org/eou and may be printed in hard copy. Subsequently, the report will be sent to the GEF Office of Evaluation for their review, appraisal and inclusion on the GEF website.

5. Resources and schedule of the evaluation

This final evaluation will be undertaken by an international evaluator contracted by the Evaluation and Oversight Unit, UNEP. The contract for the evaluator will begin on ddmmyyy and end on ddmmyyyy (# days) spread over # weeks (# days of travel, to {country (ies)}, and # days desk study). The evaluator will submit a draft report on ddmmyyyy to UNEP/EOU, the UNEP/DGEF Task Manager, and key representatives of the executing agencies. Any comments or responses to the draft report will be sent to UNEP / EOU for collation and the consultant will be advised of any necessary revisions. Comments to the final draft report will be sent to the consultant by ddmmyyyy after which, the consultant will submit the final report no later than ddmmyyyy.

The evaluator will after an initial telephone briefing with EOU and UNEP/GEF conduct initial desk review work and later travel to {country(ies)} and meet with project staff at the

beginning of the evaluation. Furthermore, the evaluator is expected to travel to {country(ies)} and meet with representatives of the project executing agencies and the intended users of project's outputs.

In accordance with UNEP/GEF policy, all GEF projects are evaluated by independent evaluators contracted as consultants by the EOU. The evaluator should have the following qualifications:

The evaluator should not have been associated with the design and implementation of the project in a paid capacity. The evaluator will work under the overall supervision of the Chief, Evaluation and Oversight Unit, UNEP. The evaluator should be an international expert in { } with a sound understanding of { } issues. The consultant should have the following minimum qualifications: (i) experience in {} issues; (ii) experience with management and implementation of { } projects and in particular with { } targeted at policy-influence and decision-making; (iii) experience with project evaluation. Knowledge of UNEP programmes and GEF activities is desirable. Knowledge of {specify language(s)} is an advantage. Fluency in oral and written English is a must.

6. Schedule Of Payment

The consultant shall select one of the following two contract options:

Lump-Sum Option

The evaluator will receive an initial payment of 30% of the total amount due upon signature of the contract. A further 30% will be paid upon submission of the draft report. A final payment of 40% will be made upon satisfactory completion of work. The fee is payable under the individual Special Service Agreement (SSA) of the evaluator and **is inclusive** of all expenses such as travel, accommodation and incidental expenses.

Fee-only Option

The evaluator will receive an initial payment of 40% of the total amount due upon signature of the contract. Final payment of 60% will be made upon satisfactory completion of work. The fee is payable under the individual SSAs of the evaluator and is **NOT** inclusive of all expenses such as travel, accommodation and incidental expenses. Ticket and DSA will be paid separately.

In case, the evaluator cannot provide the products in accordance with the TORs, the timeframe agreed, or his products are substandard, the payment to the evaluator could be withheld, until such a time the products are modified to meet UNEP's standard. In case the evaluator fails to submit a satisfactory final product to UNEP, the product prepared by the evaluator may not constitute the evaluation report.

Annex 1 to Appendix 9: OVERALL RATINGS TABLE

Criterion	Evaluator's Summary Comments	Evaluator's Rating
A. Attainment of project objectives and results (overall rating) **Sub criteria (below)**		
A. 1. Effectiveness		
A. 2. Relevance		
A. 3. Efficiency		
B. Sustainability of Project outcomes (overall rating) **Sub criteria (below)**		
B. 1. Financial		
B. 2. Socio Political		
B. 3. Institutional framework and governance		
B. 4. Ecological		
C. Achievement of outputs and activities		
D. Monitoring and Evaluation (overall rating) **Sub criteria (below)**		
D. 1. M&E Design		
D. 2. M&E Plan Implementation (use for adaptive management)		
D. 3. Budgeting and Funding for M&E activities		
E. Catalytic Role		
F. Preparation and readiness		
G. Country ownership / drivenness		
H. Stakeholders involvement		
I. Financial planning		
J. Implementation approach		
K. UNEP Supervision and backstopping		

RATING OF PROJECT OBJECTIVES AND RESULTS

Highly Satisfactory (HS): The project had no shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Satisfactory (S): The project had minor shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Moderately Satisfactory (MS): The project had moderate shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Moderately Unsatisfactory (MU): The project had significant shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Unsatisfactory (U) The project had major shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Highly Unsatisfactory (HU): The project had severe shortcomings in the achievement of its objectives, in terms of relevance, effectiveness or efficiency.

Please note: Relevance and effectiveness will be considered as critical criteria. The overall rating of the project for achievement of objectives and results **may not be higher** than the

lowest rating on either of these two criteria. Thus, to have an overall satisfactory rating for outcomes a project must have at least satisfactory ratings on both relevance and effectiveness.

RATINGS ON SUSTAINABILITY

A. Sustainability will be understood as the probability of continued long-term outcomes and impacts after the GEF project funding ends. The Terminal evaluation will identify and assess the key conditions or factors that are likely to contribute or undermine the persistence of benefits after the project ends. Some of these factors might be outcomes of the project, i.e. stronger institutional capacities, legal frameworks, socio-economic incentives /or public awareness. Other factors will include contextual circumstances or developments that are not outcomes of the project but that are relevant to the sustainability of outcomes.

Rating system for sustainability sub-criteria

On each of the dimensions of sustainability of the project outcomes will be rated as follows.

Likely (L): There are no risks affecting this dimension of sustainability.

Moderately Likely (ML). There are moderate risks that affect this dimension of sustainability.

Moderately Unlikely (MU): There are significant risks that affect this dimension of sustainability

Unlikely (U): There are severe risks that affect this dimension of sustainability.

According to the GEF Office of Evaluation, all the risk dimensions of sustainability are deemed critical. Therefore, overall rating for sustainability will not be higher than the rating of the dimension with lowest ratings. For example, if a project has an Unlikely rating in any of the dimensions then its overall rating cannot be higher than Unlikely, regardless of whether higher ratings in other dimensions of sustainability produce a higher average.

RATINGS OF PROJECT M&E

Monitoring is a continuing function that uses systematic collection of data on specified indicators to provide management and the main stakeholders of an ongoing project with indications of the extent of progress and achievement of objectives and progress in the use of allocated funds. Evaluation is the systematic and objective assessment of an on-going or completed project, its design, implementation and results. Project evaluation may involve the definition of appropriate standards, the examination of performance against those standards, and an assessment of actual and expected results.

The Project monitoring and evaluation system will be rated on 'M&E Design', 'M&E Plan Implementation' and 'Budgeting and Funding for M&E activities' as follows:

Highly Satisfactory (HS): There were no shortcomings in the project M&E system. Satisfactory(S): There were minor shortcomings in the project M&E system.

Moderately Satisfactory (MS): There were moderate shortcomings in the project M&E system.

Moderately Unsatisfactory (MU): There were significant shortcomings in the project M&E system.

Unsatisfactory (U): There were major shortcomings in the project M&E system.

Highly Unsatisfactory (HU): The Project had no M&E system.

"M&E plan implementation" will be considered a critical parameter for the overall assessment of the M&E system. The overall rating for the M&E systems will not be higher than the rating on "M&E plan implementation."

All other ratings will be on the GEF six point scale.

GEF Performance Description		Alternative description on the same scale
HS	= Highly Satisfactory	Excellent
S	= Satisfactory	Well above average
MS	= Moderately Satisfactory	Average
MU	= Moderately Unsatisfactory	Below Average
U	= Unsatisfactory	Poor
HU	= Highly Unsatisfactory	Very poor (Appalling)

Annex 2 to Appendix 9: Co-financing and Leveraged Resources

Co financing (Type/Source)	IA own Financing (mill US$)		Government (mill US$)		Other* (mill US$)		Total (mill US$)		Total Disbursement (mill US$)	
	Planned	**Actual**	**Planned**	**Actual**	**Planned**	**Actual**	**Planned**	**Actual**	**Planned**	**Actual**
– Grants										
– Loans/Concessional (compared to market rate)										
– Credits										
– Equity investments										
– In-kind support										
– Other (*) - - - - -										
Totals										

Co-financing (basic data to be supplied to the consultant for verification)

* Other is referred to contributions mobilized for the project from other multilateral agencies, bilateral development cooperation agencies, NGOs, the private sector and beneficiaries.

Leveraged Resources

Leveraged resources are additional resources—beyond those committed to the project itself at the time of approval—that are mobilized later as a direct result of the project. Leveraged resources can be financial or in-kind and they may be from other donors, NGO's, foundations, governments, communities or the private sector. Please briefly describe the resources the project has leveraged since inception and indicate how these resources are contributing to the project's ultimate objective.

Table showing final actual project expenditure by activity to be supplied by the UNEP Fund management Officer. (insert here)

Annex 3 to Appendix 9

Review of the Draft Report

Draft reports submitted to UNEP EOU are shared with the corresponding Programme or Project Officer and his or her supervisor for initial review and consultation. The DGEF staff and senior Executing Agency staff provide comments on the draft evaluation report. They may provide feedback on any errors of fact and may highlight the significance of such errors in any conclusions. The consultation also seeks agreement on the findings and recommendations. UNEP EOU collates the review comments and provides them to the evaluators for their consideration in preparing the final version of the report. General comments on the draft report with respect to compliance with these TOR are shared with the reviewer.

Quality Assessment of the Evaluation Report

All UNEP GEF Mid Term Reports are subject to quality assessments by UNEP EOU. These apply GEF Office of Evaluation quality assessment and are used as a tool for providing structured feedback to the evaluator.

The quality of the draft evaluation report is assessed and rated against the following criteria:

GEF Report Quality Criteria	**UNEP EOU Assessment**	**Rating**
A. Did the report present an assessment of relevant outcomes and achievement of project objectives in the context of the focal area program indicators if applicable?		
B. Was the report consistent and the evidence complete and convincing and were the ratings substantiated when used?		
C. Did the report present a sound assessment of sustainability of outcomes?		
D. Were the lessons and recommendations supported by the evidence presented?		
E. Did the report include the actual project costs (total and per activity) and actual co-financing used?		
F. Did the report include an assessment of the quality of the project M&E system and its use for project management?		
UNEP EOU additional Report Quality Criteria	**UNEP EOU Assessment**	**Rating**
G. Quality of the lessons: Were lessons readily applicable in other contexts? Did they suggest prescriptive action?		
H. Quality of the recommendations: Did recommendations specify the actions necessary to correct existing conditions or improve operations ('who?' 'what?' 'where?' 'when?)'. Can they be implemented? Did the recommendations specify a goal and an associated performance indicator?		
I. Was the report well written? (clear English language and grammar)		
J. Did the report structure follow EOU guidelines, were all requested Annexes included?		
K. Were all evaluation aspects specified in the TORs adequately addressed?		
L. Was the report delivered in a timely manner		

GEF Quality of the MTE report = 0.3*(A + B) + 0.1*(C+D+E+F)
EOU assessment of MTE report = 0.3*(G + H) + 0.1*(I+J+K+L)

Combined quality Rating = (2* 'GEF EO' rating + EOU rating)/3

The Totals are rounded and converted to the scale of HS to HU

Rating system for quality of terminal evaluation reports

1A number rating 1-6 is used for each criterion: Highly Satisfactory = 6, Satisfactory = 5, Moderately Satisfactory = 4, Moderately Unsatisfactory = 3, Unsatisfactory = 2, Highly Unsatisfactory = 1, and unable to assess = 0.

Annex 4 to Appendix 9

GEF Minimum requirements for M&E

Minimum Requirement 1: Project Design of M&E[3]

All projects must include a concrete and fully budgeted monitoring and evaluation plan by the time of Work Program entry (full-sized projects) or CEO approval (medium-sized projects). This plan must contain at a minimum:

- SMART (see below) indicators for project implementation, or, if no indicators are identified, an alternative plan for monitoring that will deliver reliable and valid information to management
- SMART indicators for results (outcomes and, if applicable, impacts), and, where appropriate, corporate-level indicators
- A project baseline, with:
  - a description of the problem to address
  - indicator data
  - or, if major baseline indicators are not identified, an alternative plan for addressing this within one year of implementation
- An M&E Plan with identification of reviews and evaluations which will be undertaken, such as mid-term reviews or evaluations of activities
- An organizational setup and budgets for monitoring and evaluation.

[3] http://gefweb.org/MonitoringandEvaluation/MEPoliciesProcedures/MEPTools/meptstandards.html

Minimum Requirement 2: Application of Project M&E

- Project monitoring and supervision will include implementation of the M&E plan, comprising:
- Use of SMART indicators for implementation (or provision of a reasonable explanation if not used)
- Use of SMART indicators for results (or provision of a reasonable explanation if not used)
- Fully established baseline for the project and data compiled to review progress
- Evaluations are undertaken as planned
- Operational organizational setup for M&E and budgets spent as planned.

SMART INDICATORS GEF projects and programs should monitor using relevant performance indicators. The monitoring system should be "SMART":

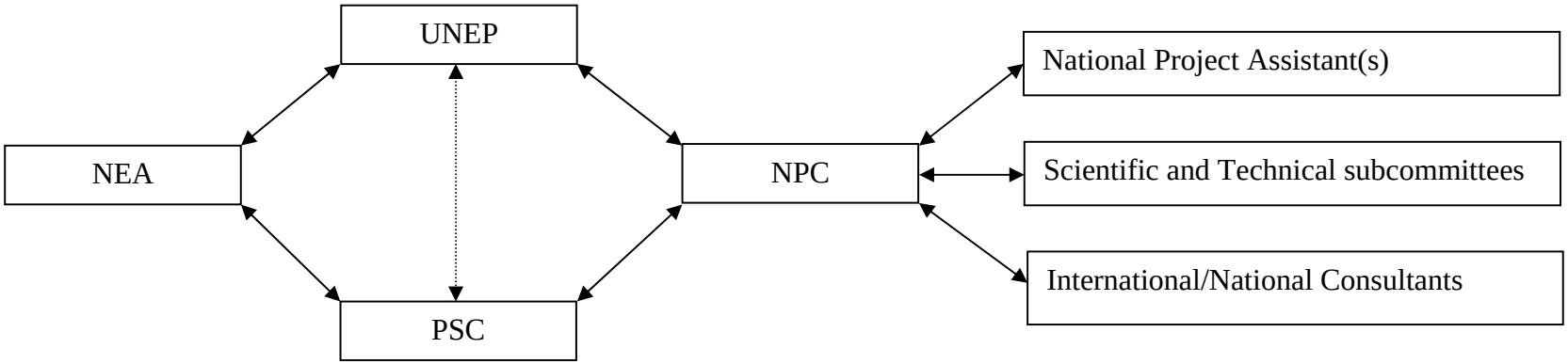
1. **Specific**: The system captures the essence of the desired result by clearly and directly relating to achieving an objective, and only that objective.
2. **Measurable:** The monitoring system and its indicators are unambiguously specified so that all parties agree on what the system covers and there are practical ways to measure the indicators and results.
3. **Achievable and Attributable:** The system identifies what changes are anticipated as a result of the intervention and whether the result(s) are realistic. Attribution requires that changes in the targeted developmental issue can be linked to the intervention.
4. **Relevant and Realistic:** The system establishes levels of performance that are likely to be achieved in a practical manner, and that reflect the expectations of stakeholders.
5. **Time-bound, Timely, Trackable, and Targeted:** The system allows progress to be tracked in a cost-effective manner at desired frequency for a set period, with clear identification of the particular stakeholder group to be impacted by the project or program.

Annex 5 to Appendix 9

List of intended additional recipients for the Terminal Evaluation (to be completed by the IA Task Manager)

Name	Affiliation	Email
Aaron Zazuetta	GEF Evaluation Office	azazueta@thegef.org
Government Officials		
GEF Focal Point(s)		
Executing Agency		
Implementing Agency		
Carmen Tavera	UNEP DGEF Quality Assurance Officer	

Appendix 10: Decision making flowchart and organigram



UNEP: United Nations Environmental Programme
NEA: National Executing Agency (Ministry of Environment and Physical Planning, Macedonia)
PSC: Project Steering Committee
NPC: National Project Coordinator

APPENDIX 11: TERMS OF REFERENCE

Terms of Reference for:

1. **National Executing Agency (NEA)**
2. **Project Steering Committee (PSC)**
3. **National Project Coordinator (NPC)**
4. **Project Assistant(s)**

1) The **National Executing Agency (NEA),** in addition to other duties given to it by the National Government, will:
   a) Appoint a National Project Coordinator (NPC) taking into account the sustainability of the national biosafety activities after the project completion;
   b) Establish the Project Steering Committee (PSC) ;
   c) Provide the necessary scientific, technical, financial and administrative support necessary to the PSC so that it can carry out its work in close collaboration with the relevant government agencies and other stakeholders and implementing partners;

2) The **Project Steering Committee (PSC)** will be established by the National Executing agency (NEA) in consultation with all Biosafety relevant stakeholders to advice and guide the implementation of the project. The functions of the PSC are to:

   a) Provide overall advice on the implementation of the project;
   b) Oversee the progress of the project execution to ensure that its objectives will be met by the end of the project;
   c) Make recommendation to UNEP when revision of the result framework, work plan or M&E plan are needed;
   d) Catalyse inter-departmental and broader national stakeholder support towards achieving the objectives of the project.
   e) Develop a common understanding on what is necessary to accelerate the establishment of the national biosafety institutional structure;
   f) Approve the detailed work plan and budget provided by the NPC ;
   g) Mobilize the necessary expertise in collaboration with the NEA and UNEP needed for the execution of the national project;
   h) Ensure that government policy is reflected in all documentation and outputs from the national project ;
   i) Act as discussion forum to air differences and listen to varieties of views and record the process.

3) The National Project Coordinator **(NPC) will** be appointed by the NEA and will therefore report to the NPD and the PSC. The NPC shall:

   a) Draw up detailed work plans and budget under the supervision of the NPD and PSC ;
   b) Communicate with authorities, institutions and government departments concerned in close collaboration with the NDP and the PSC;
   c) Search, create and maintain linkages with other related national programs and projects;
   d) Draw up and supervise terms of reference for consultants and experts in the execution of components of the national project;
   e) Organize, appoint and management of the consultants and experts;
   f) Oversee the technical and financial management of the national project including supervision of allocation of overall resources and if necessary, submitting proposals for budget review to PSC and UNEP ;
   g) Oversee responsibility and reporting on monitoring and evaluation processes as per appendix 7

h) Coordinate the work of all the stakeholders under the supervision of NEA and PSC and in collaboration with UNEP;
i) Provide information to the NPD and the PSC on all the activities of the government, private and public sectors which have an impact on the safe use of modern biotechnology ;
j) Draw up and submit regular progress reports financial reports and Draft PIR reports to UNEP.

4) The **project assistants (PA)** will carry out the following tasks:

a) 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;
b) Assist with the organisation of the National Coordinating committee meetings;
c) Assist in drafting Terms of Reference for the National Project components consultants and experts;
d) Assist the NPC ensuring that all activities are carried out on time and within budget to achieve stated outputs;
e) Assist in providing information to the PSC about all government private and public sector activities which impact on any use of modern biotechnology;
f) Assist in the preparation of the project monitoring and evaluation plan;
g) Assist with the identification of appropriate project indicators able to reflect progress of activities as well as impact;
h) Assist in capturing and incorporating recommendations from PSC meetings into project execution and monitoring and evaluation plan;
i) Assist with the preparation of the terminal report and other project closure procedures at project completion;
j) Attend workshops and consultations as appropriate;
k) Any other task assigned.

Republic of Macedonia
Ministry of Environment and physical planning

Republic of Macedonia
Ministry of Environment and physical planning

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Archive No. 11-8263/1

Date: 20.08.2010

To: Maryam Niamir-Fuller
Director
Division of Global Environment Facility
GEF Coordination, UNEP
PO Box 30552 Nairobi, Kenya
Email: mayam.niamir-fuller@unep.org
Fax: (254 20) 762-4041

Re: Co-finance commitment for the Support for the Implementation of the National Biosafety Framework Project for Republic of Macedonia

Respectable,

As a signatory of the Convention on Biological Diversity and its Cartagena Protocol on Biosafety, Republic of Macedonia attaches a great importance to the implementation of this Protocol.

The Government of Republic of Macedonia therefore, through the Ministry of Environment and Physical Planning and Administration for Environment, is committed to contribute in-kind through 3 years period the amount of at least US$ 236,000 towards the total cost of US$ 643,000 for the implementation of the National Biosafety Framework Project for Republic of Macedonia.

We thank you in appreciation for your continued support,

Mrs. Daniela RENDEVSKA
GEF Operational focal point
Head of Unit for Bilateral and Multilateral Cooperation
Ministry of Environment and Physical Planning
Goce Delcev bb,
Skopje 1000
Republic of Macedonia
Tel.Fax: +389 2 3215 438
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Copy to :
Mrs.Marija DIRLEVSKA CALOVSKA
Focal point of the Cartagena Protocol on Biosafety
Department of Nature
Administration for Environment
Ministry of Environment and Physical Planning
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MINISTRY FOR ENVIRONMENT AND PHYSICAL PLANNING
REPUBLIC OF MACEDONIA

08/31/09

РЕПУБЛИКА МАКЕДОНИЈА
МИНИСТЕРСТВО ЗА ЖИВОТНА СРЕДИНА
И ПРОСТОРНО ПЛАНИРАЊЕ
Бр. 11-8185/1
24.09. 20 09 год.
СКОПЈЕ

To:
Maryam Niamir-Fuller
Director
UNEP Division of Global Environment Facility (GEF) Coordination
PO Box 30552 Nairobi, Kenya
Email: maryam.niamir-fuller@unep.org
Fax: (254 20) 762-4041

Subject: Support for the Implementation of the National Biosafety Framework of FYR of Macedonia

In my capacity as GEF Operational Focal Point for the **FYR of Macedonia**, I confirm that the above project proposal (a) is in accordance with the government's national priorities and the commitments made by the **FYR of Macedonia** under the relevant global environmental conventions and (b) has been discussed with relevant stakeholders, including the global environmental convention focal points, in accordance with GEF's policy on public involvement.

Accordingly, I am pleased to endorse the preparation of the above project proposal with the support of UNEP. If approved, the proposal will be prepared and implemented by Ministry of Environment and Physical Planning. Further, I request UNEP.to provide a copy of the project document for information of this before it is submitted to the GEF Secretariat for CEO endorsement.

I understand that the total GEF financing being requested for this project is $447,700, inclusive of project preparation grant (PPG), if any, and Agency fee (10%) to UNEP for project cycle management services associated with this project.

I consent to the utilization of the following indicative allocations available to the **FYR of Macedonia** in GEF-4 under the GEF Resource Allocation Framework to cover the GEF project preparation and implementation as well as the associated Agency fees for this project.

Biosafety: $ Biodiversity: $447,700

Sincerely,

Mrs. Daniela Rendevska
(Operational Focal Point)
Head of Unit for Bilateral and Multilateral Cooperation
Ministry of Environment and Physical Planning
Goce Delcev, bb
Skopje 1000
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Tel/Fax: +389 2 3215 373
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Copy to:
Focal Point of the Cartagena Protocol on Biosafety

Mrs. Marija DIRLEVSKA CALOSKA
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Applying the GEF Tracking Tools in GEF-4

Objective: To measure progress in achieving the impacts and outcomes established at the portfolio level under the biodiversity focal area. The following targets and indicators are being tracked for all GEF-4 projects submitted under Strategic Objective Three and the associated Strategic Programs.

Outcome Indicators for Strategic Objective Three and Associated Strategic Programs

Strategic Objective	**Expected Long-Term Impacts**	**Indicators**
To safeguard biodiversity	Potential risks posed to biodiversity from living modified organisms are avoided or mitigated Potential risks posed to biodiversity from invasive alien species are avoided or mitigated	Biosafety: • Each request for intentional transboundary movement or domestic use is processed through a regulatory and administrative framework aligned with the CPB • For each request for intentional transboundary movement or domestic use risk assessments carried out in accordance with the CPB • For each request for intentional transboundary movement or domestic use, measures and strategies to manage risks established Invasive Alien Species: • Number of point-of-entry detections • Number of early eradications • Number of successful prevention and control programs
Strategic Programs for GEF-4	**Expected Outcomes**	**Indicators**
6. Building capacity for the implementation of the Cartagena Protocol on Biosafety	• Operational national biosafety decision-making systems that contribute to the safe use of biotechnology in conformity with the provisions and decisions of the CPB	• Percentage of participating countries with regulatory and policy framework in place • Percentage of participating countries that have established a National Coordination Mechanism • Percentage of participating countries with administrative frameworks in place • Percentage of participating countries with risk assessment and risk management strategies for the safe transfer, handling and use of living modified organisms (LMOs), specifically focused on transboundary movements • Percentage of participating countries that have carried out risk assessments • Percentage of participating countries that fully participate and share information on the Biosafety Clearing House (BCH)

Strategic Programs for GEF-4	Expected Outcomes	Indicators
7. Prevention, control, and management of invasive alien species (IAS)	• Operational IAS management frameworks that mitigate impact of IAS on biodiversity and ecosystem services	• National coordination mechanisms to assist with the design and implementation of national strategies for IAS • National strategies that inform policies, legislation, regulations, and management • Regulatory and policy frameworks for IAS in place • Point of detection mechanisms in place • Incorporation of environmental considerations with regards to IAS into existing risk assessment procedures • Identification and management of priority pathways for invasions

Rationale: Project data from the GEF-4 project cohort will be aggregated for analysis of directional trends and patterns at a portfolio-wide level to inform the development of future GEF strategies and to report to GEF Council on portfolio-level performance in the biodiversity focal area.

Structure of Tracking Tool: Each tracking tool requests background and coverage information on the project and specific information required to track the indicator sets listed above.

Guidance in Applying GEF Tracking Tools: GEF tracking tools are applied three times: at CEO endorsement[1], at project mid-term, and at project completion.

In GEF-4, we expect that projects will be fully aligned with specific Strategic Objectives and support Strategic Programs under each Strategic Objective hence only one tracking tool will need to be completed.

On *very rare occasions*, projects make substantive contributions to more than one strategic objective. In these instances, the tracking tools for the relevant strategic objectives should be applied. It is important to keep in mind that the objective is to capture the full range of a project's contributions to delivering on the targets set for each of the strategic priorities. The GEF Implementing Agency/Executing Agency will guide the project teams in the choice of the tracking tools. Please submit all information on a single project as one package (even where more than one tracking tool is applied).

Multi-country projects may face unique circumstances in applying the tracking tools. The GEF requests that multi-country projects complete one tracking tool per country involved in the project, based on the project circumstances and activities in each respective country. The completed forms for each country should then be submitted as one package to the GEF. Global projects which do not have a country focus, but for which the tracking tool is applicable, should complete the tracking tool as comprehensively as possible.

The tracking tool does not substitute or replace project level M&E processes, or GEF Implementing Agencies'/Executing Agencies' own monitoring processes. Project managers, consultants and project evaluators will likely be the most appropriate individuals to complete the

[1] For Medium Sized Projects when they are submitted for CEO approval.

Tracking Tool, in collaboration with other members of the project team, since they would be most knowledgeable about the project.

Submission: The finalized tracking tool will be cleared by the GEF Implementing Agencies and Executing Agencies before submission. The tracking tool is to be submitted to the GEF Secretariat at three points:

1.) With the project document at CEO endorsement[2];
2.) Within 3 months of completion of the project's mid-term evaluation or report; and
3.) With the project's terminal evaluation or final completion report, and no later than 6 months after project closure.

[2] For Medium Sized Projects when they are submitted for CEO approval.

I. Project General Information

1. Project Name: **Capacity building for the Implementation of the National Biosafety Framework of Macedonia**
2. Project Type (MSP or FSP): **MSP**
3. Project ID (GEF):
4. Project ID (IA):
5. Implementing Agency: **UNEP**
6. Country(ies): **Macedonia**

Name of reviewers completing tracking tool and completion dates:

	Name	**Title**	**Agency/Institution**
Work Program Inclusion	**Jasmina Ginovska**	**National Project Coordinator**	**Ministry of Environment and Physical Planning**
Project Mid-term			
Final Evaluation/project completion			

7. Project duration: ***Planned***___3__ years ***Actual*** _____ years

8. Lead Project Executing Agency (ies): **Ministry of Environment and Physical Planning**

9. GEF Strategic Program:
Building capacity for the implementation of the Cartagena Protocol on Biosafety (SP 6)

Strategic Program 6: Building capacity for the implementation of the Cartagena Protocol on Biosafety Tracking Tool Guidance Note

Purpose of the Tracking Tool

The Biosafety Tracking Tool has been developed to help track and monitor progress in the achievement of the primary outcome of Strategic Program Six of the GEF-4 Biodiversity Strategy: "Operational national biosafety decision-making systems that contribute to the safe use of modern biotechnology in conformity with the provisions and decisions of the CPB." This outcome will be achieved by building capacity to implement the CPB and takes into account the guidance from the CPB and lessons and experiences emerging from the GEF biosafety portfolio. Priority is given to activities for the implementation of the CPB that are specified in the COP guidance to the GEF with respect to biosafety, in particular the key elements in the *Updated Action Plan for Building Capacities for the Effective Implementation of the CPB*, agreed to at the third COP serving as the Meeting of the Parties to the CPB (COP-MOP-3), and identified in a country's stock-taking analysis. The complete list of activities to be supported under this strategic objective can be found in the biosafety strategy document at: http://gefweb.org/Documents/Council_Documents/GEF_30/documents/C.30.8.Rev.1StrategyforFinancingBiosafety.pdf

Guidance on Applying the Biosafety Tracking Tool

The Tracking Tool contains a set of questions that have been designed to be easily answered by project staff and project evaluators. It depicts a best-case scenario of the required components of a fully operational biosafety framework, and, within each component, a continuum of progress towards a biosafety framework that is fully effective.

As with the other tracking tools applied in the GEF biodiversity portfolio, the application of the tool is meant to facilitate an iterative process whereby the project staff and project evaluators carefully discuss each question about the biosafety framework to arrive at a carefully considered assessment, and in doing so, identify concrete steps forward for improvement. In most cases, a group of project staff, GEF agency staff, (and the project evaluators in the case of the application of the tool at the mid-term and final evaluation) should be involved in answering the questions in the Tracking Tool.

When the assessment is undertaken at the mid-term and the final evaluation, we recommend that some of the same team members who undertook previous assessments be involved to provide continuity of analysis. Where this is not possible the information provided by previous assessors in the comments section of the Tracking Tool will be particularly valuable in guiding the assessment and ensuring consistency in the evaluation being made.

Structure and content of the Tracking Tool

The Tracking Tool addresses eight main issues in one assessment form:

1) Biosafety Policy;
2) Biosafety Regulatory Regime;
3) Administrative System;
4) Risk Assessment and Decision-making;
5) Follow-up and Monitoring;

6) Public awareness;
7) Education; and
8) Participation

Assessment Form: The assessment is structured around eight (8) questions presented in table format which includes three columns for recording details of the assessment, **all of which should be completed**.

Questions and scores:

The assessment is made by assigning a simple score ranging between 0 (poor) to 4 (excellent) in response to a series of eight questions that measure progress in the eight main issues listed above: 1) Biosafety Policy; 2) Biosafety Regulatory Regime; 3) Administrative System; 4) Risk Assessment and Decision-making; 5) Follow-up and Monitoring; 6) Public awareness; 7) Education; and 8) Participation.

Five alternative answers are provided for each question to help assessors to make judgments as to the level of score given. This is, inevitably, an approximate process and there will be situations in which none of the five alternative answers appear to fit the project conditions very precisely. We ask that you choose the one answer that is nearest and use the comment/explanation section to elaborate. The maximum score from the eight main questions is 32. A final total of the score from completing the assessment form can be calculated as a percentage of 32.

The whole concept of "scoring" progress is however fraught with difficulties and possibilities for distortion. The current system assumes, for example, that all the questions cover issues of equal weight, whereas this may not necessarily be the case. Scores will therefore provide a better assessment of effectiveness if calculated as a percentage for each of the elements of a biosafety framework.

Most importantly, the assessment, when applied over time in the context of one project, allows us to gauge progress in achieving the strategic program's expected outcome. GEF will use this information and subsequent analysis in assessing and better understanding the design of biosafety projects, the strategic program itself, and the tracking tool as a means to measure progress.

Comment/explanation:

The **comment/explanation** box next to each question score allows for ***qualitative judgments to be explained*** in more detail. This could range from local staff knowledge (in many cases, staff knowledge will be the most informed and reliable source of knowledge), a reference document, monitoring results or external studies and assessments – the point being to give anyone reading the report an idea of why the assessment was made.

It is **very important** that this box be completed – it can provide greater confidence in the results of the assessment by making the basis of decision-making more transparent. More importantly, it provides a reference point and information for local staff in the future. This column also allows for ***comments***, such as why a particular question was not answered when completing the questionnaire.

Next Steps:

For each question respondents are also asked to identify any intended actions that will improve performance of the biosafety framework.

Strategic Program 6: Building capacity for the implementation of the Cartagena Protocol on Biosafety Tracking Tool

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
Biosafety Policy	***Q1) Has a biosafety policy been developed and is it being fully implemented?***			
	Response Selection			
	A stand alone biosafety policy does not exist	0		
	A stand alone biosafety policy has been produced	1		
	A stand alone biosafety policy has been produced and has been formally adopted by the government	2	Law on GMO adopted in 2008 (OG of RM 35/08) and gives the basic principles of the biosafety policy. There is no separate policy document as such.	To strengthen institutional capacity for implementation of the Law.
	A legally approved biosafety strategy has been incorporated into broader sectoral policies (e.g. agriculture, biotechnology, science and technology, health, etc) and is being enforced	3		
	A biosafety policy is implemented through a multi-year Action Plan that involves more than one sector of	4		

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
	Government or society.			
Biosafety Regulatory Regime	***Q2) Has a regulatory regime been developed and does it have full legal force?***			
	Response Selection			
	A regulatory regime has not been developed	0		
	Interim measures for biosafety decision making, including some modification of existing regulations, have been put in place.	1		
	A regulatory regime has been developed and adopted but does not yet have full legal force	2	Regulatory regime has been initiated, Law has been adopted in 2008, but secondary legal acts still need to be drafted and	Completion and adoption of all secondary acts

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
			adopted	
	The regulatory regime has full legal force, is operational and linked to the administrative system -i.e. used for decisions	3		
	The regulatory regime covers all the types of LMOs and transboundary movements referred to in the Cartagena Protocol, including agreements with Non-Parties	4		
Administrative System	***Q3) Is an administrative system in place and fully operational?***			
	Response Selection			
	Focal Points and National Competent Authorities not appointed nor available via BCH	0		

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
	All Focal Points and National Competent Authorities appointed, and roles & responsibilities stated and available on BCH	1		
	Procedures for handling requests have been designed, legally adopted, and made available to the public.	2	As regulated in the Law on GMO leading competent authority is the Ministry of environment and physical planning. Decisions are made in cooperation with the Ministry of Health and Ministry of agriculture, forestry and water economy. For decisions regarding the areas of use of GMOs excluded by the provisions of the Law on Genetically Modified Organisms (medicinal products, food and feed), the Ministry of Agriculture, Forestry and Water Economy and the Ministry of Health are competent. There are two professional bodies for professional assistance in the area of GMO management. With the Decision for establishment of the Commission for management of Genetically Modified Organism (Official Gazette of RM 11/2009) the Government founded team of experts that shall provide professional support in monitoring the status and development in the area of GMO management. With the Decision for establishment	System in place in paper as set in GMO law, but needs secondary legal acts to be operational.

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
			of Scientific Committee for Genetically Modified Organism (Official Gazette of RM 11/2009) the Government founded team of experts that shall provide professional support for ministries competent for decisions in regards to the management of GMO's specifically addressing GMO for contained use, deliberate release into the environment and placing on the market.	
	Requests have been received, processed, and decisions communicated to the BCH. Appeal procedures designed and operational.	3		
	Administrative system fully supported by national budget allocation or alternative (non-donor) system of revenue generation	4		
Risk Assessme	***Q4) Are risk assessment procedures employed and contributing to decision-making?***			

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
nt and Decision-making				
	Response selection			
	No risk assessment is applied to LMOs	0		
	Sectoral risk assessment dossiers are required to accompany LMO requests	1		
	Risk assessment/risk management system involves case-by-case analyses by scientific experts that provide recommendations to decision-making bodies. Composition and responsibilities of the decision-making bodies clearly stated and publicized.	2	Law, adopted in 2008, sets the RA/RM system, the composition and the responsibilites of the system.	Even though law sets the main principles and responsibilities, the system is not yet operational and needs secondary legal acts to be drafted and adopted, and relevant training.
	Decisions on LMOs are integrated across sectors (e.g. take into account risks to human health)	3		

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
	Decision-making system allows for socio-economic considerations and for review of decisions based on new evidence	4		
Follow-up and Monitoring	***Q5) Does an operational follow-up and monitoring system exist?***			
	Response Selection			
	No system for follow-up and monitoring exists	0	Law sets the basic principles and responsible authorities, but the system is neither finalised nor functional yet.	Building institutional and strengthen human capacity to follow up and monitor, including risk assessment for field trials
	Institutional and human capacity in	1		

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
	place to follow-up and monitor, including Risk Management for field-trials and post-release			
	Compliance mechanisms for Risk Management established	2		
	Liability and redress mechanisms in place	3		
	Decisions, risk management plans, and reports on compliance and liability have been posted to the BCH	4		
Public awareness, educatio	**I. Awareness** *Q6) Is information on LMOs made available to public?*	0		

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
and participation				
	Response Selection			
	Little or no official information on LMOs available to the general public	0		
	Information on LMOs generally available in at least one national language	1		
	Information on LMOs generally available in at least one national language and is kept updated	2	Information available on national BCH	To organize awareness raising campaign with strengthen coordination of Focal Point availability appointed for providing regular information to public.
	Information on LMOs is used for awareness-raising campaigns	3		
	Survey results on levels of public awareness available	4		

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
	II. Education *7) Has coursework and training on biosafety been integrated into higher education?*			
	Response Selection			
	No modern biotechnology and biosafety available in the formal (i.e. technical, academic, extramural) education system.	0		
	Basic modern biotechnology and biosafety information included in the curricula at technical and college levels.	1		
	Dedicated short-term courses on biosafety available for government staff at technical schools and higher education institutions.	2		
	National association for biosafety established	3		
	Undergraduate and graduate degree programs offering concentrations and/or degree programs on modern biotechnology, including biosafety	4	Within the universities programmes there are Biotechnology, Food safety, and Genetic curricula covered for graduate and post graduate students. High school programmes covers general aspect of genetic within the regular Biology schedule.	Short term courses to government staff in planning
	III. Participation			

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
	Q8) Has the public been engaged in LMO decision-making?			
	Little or no direct involvement of public in LMO decision-making	0		
	Access to information includes other mechanisms in addition to the BCH (i.e. radio and television programs, newspapers columns, blogs, etc.).	1		
	Mechanism for public involvement in LMO decision-making established	2	Participation included through direct contact with Ministry of Environment and Physical Planning.	In planning is to open online forum on the national BCH, as well, as to intensify media (TV, radio, newspapers) coverage in order to improve the public involvement
	Evidence of level of public involvement in LMO decision-making available via BCH or other means	3		
	Regular open consultation meetings held on biosafety	4		
TOTALSCO		16		

Issue	Scoring Criteria	Score: Tick only one box per question	Comment/Explanation	Next Steps
RE				
TOTAL POSSIBLE		**32**		