Mainstreaming of Biosafety and Institutional Capacity Building to strengthen effective implementation of Cartagena Protocol on Biosafety

Review PIF and Make a recommendation

Basic project information

GEF ID

10773

Countries

India

Project Name

Mainstreaming of Biosafety and Institutional Capacity Building to strengthen effective implementation of Cartagena Protocol on Biosafety

Agencies

UNEP

Date received by PM

3/25/2021

Review completed by PM

4/14/2022
Program Manager

Hannah Fairbank
Focal Area

Biodiversity
Project Type

MSP

PIF

Part I ? Project Information

Focal area elements

1. Is the project/program aligned with the relevant GEF focal area elements in Table A, as defined by the GEF 7 Programming Directions?

Secretariat Comment at PIF/Work Program Inclusion
April 2, 2021 HF:

Yes

Agency Response
Indicative project/program description summary

2. Are the components in Table B and as described in the PIF sound, appropriate, and sufficiently clear to achieve the project/program objectives and the core indicators?

Secretariat Comment at PIF/Work Program Inclusion
December 14, 2021 HF:
Comment cleared.

April 2, 2021 HF:

Yes.

Please correct typo, first word, first project component should read "Stock taking" not stocking. In same vein, please spell out LMOs in first usage.

Agency Response
December 7, 2021

Done ? Requested changes effected
Co-financing

3. Are the indicative expected amounts, sources and types of co-financing adequately documented and consistent with the requirements of the Co-Financing Policy and Guidelines, with a description on how the breakdown of co-financing was identified and meets the definition of investment mobilized?

Secretariat Comment at PIF/Work Program Inclusion
April 2, 2021 HF:

Yes

Agency Response
GEF Resource Availability

4. Is the proposed GEF financing in Table D (including the Agency fee) in line with GEF policies and guidelines? Are they within the resources available from (mark all that apply):

Secretariat Comment at PIF/Work Program Inclusion
April 2, 2021 HF:

Yes, Agency fee is 9.5 % of $2 million grant.

Agency Response

The STAR allocation?

Secretariat Comment at PIF/Work Program Inclusion

April 2, 2021 HF:

Yes

Agency Response
The focal area allocation?

Secretariat Comment at PIF/Work Program Inclusion
April 2, 2021 HF:

Yes

Agency Response
The LDCF under the principle of equitable access?

Secretariat Comment at PIF/Work Program Inclusion NA

Agency Response
The SCCF (Adaptation or Technology Transfer)?

Secretariat Comment at PIF/Work Program Inclusion NA

Agency Response
Focal area set-aside?

Secretariat Comment at PIF/Work Program Inclusion NA

Agency Response
Impact Program Incentive?

Secretariat Comment at PIF/Work Program Inclusion NA

Agency Response
Project Preparation Grant

5. Is PPG requested in Table E within the allowable cap? Has an exception (e.g. for regional projects) been sufficiently substantiated? (not applicable to PFD)

Secretariat Comment at PIF/Work Program Inclusion
April 2, 2021 HF:

Yes, PPG and PPG fee are within allowable caps.

Agency Response
Core indicators

6. Are the identified core indicators in Table F calculated using the methodology included in the corresponding Guidelines? (GEF/C.54/11/Rev.01)

Secretariat Comment at PIF/Work Program Inclusion
December 14, 2021 HF:

Comment cleared.

April 2, 2021 HF:

1.) Please revise the word version of the PIF to also reflect the target for core indicator 11: beneficiaries. I see the target in the Portal, but the attached document version reads "monitored".

Agency Response
December 7, 2021

The targets under Indicator 11 included in the PIF to correspond to the information provided in the Portal.

Project/Program taxonomy

7. Is the project/program properly tagged with the appropriate keywords as requested in Table G?

Secretariat Comment at PIF/Work Program Inclusion
April 2, 2021 HF:

Yes

Agency Response

Part II ? Project Justification

1. Has the project/program described the global environmental/adaptation problems, including the root causes and barriers that need to be addressed?

Secretariat Comment at PIF/Work Program Inclusion

December 14, 2021 HF:
Comment cleared.

April 2, 2021 HF:

In #1.) global environmental problems section: please address "key challenges" and issues the this project, in particular, will aim to address in terms of biosafety specifically (and how related to general development challenges mentioned).

Agency Response

December 7, 2021

Key challenges: Coordinated management of biosafety and environmental releases in the area of review of applications and dedicated capacity on monitoring and enforcement under the management of State Level regulatory system. The needs to be clearly defined and operationalized at the sub-national and levels through the State Biotechnology Coordination Committees and the District Level Co ordination Committees as per the Rules 1989.

2. Is the baseline scenario or any associated baseline projects appropriately described?

Secretariat Comment at PIF/Work Program Inclusion

April 2, 2021 HF:

Yes

Agency Response

3. Does the proposed alternative scenario describe the expected outcomes and components of the project/program?

Secretariat Comment at PIF/Work Program Inclusion

April 14, 2022 HF
Comments cleared.

December 14, 2021 HF:

1.) Doesn't look like this was addressed in the PIF. Please revise and return.

2.) Comments cleared.

3.) Please articulate and include clear criteria for site selection.

April 2, 2021 HF:
1.) For each of the proposed project components please articulate a clear set of expected outcomes.

2.) Component 6 on project monitoring: Please provide a bit more detail about planned monitoring approach, framework, outcomes, application.

3.) How many pilots does the project intend to support? And what are the potential criteria for selection? Please include in project documentation.

Agency Response

April 04, 2022

The selection of sites is based on field experience and ongoing activities:

1. Ongoing field trials of Crops (Rubber and Cotton) which have reached the stage for possible commercial or deliberate release

2. Cultivated site of approved genetically modified (GM) crops.

3. GMO crops under Trade (Import and export of GM Products)

4. The opportunity to use the selected sites to test biosafety instruments, train and strengthening the State Level Biotechnology Coordination Committees (SBCC) to undertake their legally mandated monitoring and enforcement rules as designated by the Biosafety Rules.

December, 7, 2021

2.) Component 6 on project monitoring: Please provide a bit more detail about planned monitoring approach, framework, outcomes, application. Expected outcomes reviewed and updated.

Additional information provided on project monitoring.

3.) How many pilots does the project intend to support? And what are the potential criteria for selection? Please include in project documentation.

The 4 proposed pilot project sites are the States Government of Maharashtra, Telangana (GM Cotton), Assam (GM Rubber) and New Delhi (Trade Point and GM Mustard).

The criteria for selection of the proposed pilot sites were based on documented field trials and institutional structures for Handling, monitoring and enforcement of decisions on GM releases. This will be further reviewed during the PPG phase.

4. Is the project/program aligned with focal area and/or Impact Program strategies?

Secretariat Comment at PIF/Work Program Inclusion

April 2, 2021 HF:

Yes

Agency Response

5. Is the incremental/additional cost reasoning properly described as per the Guidelines provided in GEF/C.31/12?

Secretariat Comment at PIF/Work Program Inclusion

April 14, 2022 HF:

Cleared.

April 2, 2021:

Please develop the incremental reasoning a bit further to include how this project would (further) build capacity for implementation (as earlier on the MSP states the basic capacities have been built) and why this project would institutionalize whereas past projects haven't (could also be addressed in sustainability).

Agency Response

December 7, 2021

The incremental reasoning is buttressed on the principle of translation of knowledge, experience and further developments from the Federal or Union Level through the State and District levels. In addition, the previous interventions focused more on contained and confined field trials mainly in the area of agricultural biotechnology. The proposed project will further broaden the scope and build capacity in the area of environmental/commercial release not only in agriculture biotechnology but capacity to cover the management of all Living Modified organisms developed or received into India. It will also allow for supportive and institutional linkages between the GEAC in relation to Environmental releases and the State Coordination Committee which have a legal responsibility to do post approval monitoring and enforcement of permit conditions on the ground or State level. It will also allow for internalization and mainstreaming of the biosafety regulatory instruments and additional deliverables to enable India have a more dedicated and streamlined biosafety decision making and follow up processes from federal to the end users at the State Level.

6. Are the project?s/program?s indicative targeted contributions to global environmental benefits (measured through core indicators) reasonable and achievable? Or for adaptation benefits?

Secretariat Comment at PIF/Work Program Inclusion

December 14, 2021 HF:

Comment cleared. Note that target setting for Core Indicator 4 will be set during PPG.

April 2, 2021 HF:

1.) Please set targets for Core Indicator 4 (if focused at state-wide improved management of hectares via mainstreaming). If this is not possible at this time, please do so once sites have been determined during stocktaking.

Agency Response

December 7, 2021

India takes note but this request cannot be fully addressed at this stage. This issue will be undertaken during the PPG stage and is already highlighted for follow up guidance by the GoI on specific activities at the State Level at the planned pilot sites.

7. Is there potential for innovation, sustainability and scaling up in this project?

Secretariat Comment at PIF/Work Program Inclusion

April 2, 2021 HF:

Yes

Agency Response

Project/Program Map and Coordinates

Is there a preliminary geo-reference to the project?s/program?s intended location?

Secretariat Comment at PIF/Work Program Inclusion

December 14, 2021 HF:

Comment cleared. Please see request for criteria above.

April 2, 2021 HF:

There is a map of India, with two states excluded, but no sense of potential pilot sites/provinces indicated. Please see previous question about potential pilot sites and criteria. Please update map accordingly.

Agency Response

December 7, 2021

The project will be implemented in India: for activities related to State level engagement at pilot scale, States shortlisted will be further reviewed and updated based on results of stock taking assessment. States with active biotechnology programmes for development and use of LMOs and where field trials have been permitted are highlighted in the map. The North Eastern States and State of Jammu and Kashmir is excluded because currently there is not much ongoing Biotechnology research or field trials.

States Government of Maharashtra, Telangana (GM Cotton), Assam (GM Rubber) and New Delhi (Trade Point and GM Mustard) are the 4 pilot project sites proposed. The potential criteria for selection of the proposed pilot sites were selected based on documented field trials and institutional structures for Handling, monitoring and enforcement of decisions on GM releases. This will be further reviewed during the PPG phase.

Stakeholders

Does the PIF/PFD include indicative information on Stakeholders engagement to date? If not, is the justification provided appropriate? Does the PIF/PFD include information about the proposed means of future engagement?

Secretariat Comment at PIF/Work Program Inclusion

December 14, 2021 HF:

Comment cleared.

April 2, 2021 HF:

Please provide basic information about stakeholder engagement to date in developing this PIF.

Agency Response

December 7, 2021

The key stakeholders consulted during the PIF development beside Government Ministries, Agencies and Departments are listed below:

1) Federation of Seed Industry;

2) Confederation of Indian Industry
3) Federation of Indian Chambers of Commerce and Industries;
4) National Seeds Corporation;
5) All India Biotech Association (AIBA)
6) National Biodiversity Authority;
7) Biotechnology Consortium of India Limited (BCIL)
8) Institute of Forest Genetics and Tree Breeding (IFGTB)

Gender Equality and Women?s Empowerment

Is the articulation of gender context and indicative information on the importance and need to promote gender equality and the empowerment of women, adequate?

Secretariat Comment at PIF/Work Program Inclusion

June 9, 2022 HF:
Comment cleared.

April 21, 2022:

Please more clearly outline the plans to assess/analyze gender issues during PPG to inform project development.

December 14, 2021 HF:
Comment cleared.

April 2, 2021 HF:

Please include a discussion of gender that is customized to the MSP focus, e.g. biosafety.

Agency Response

December 7, 2021

Gender based Issues on Biosafety including governance, capacity support, regulatory responses, use, monitoring and enforcement, outreach and potential entry points are highlighted in the updated PIF for gender equality considerations in relation to the proposed biosafety intervention.

The 33% of the Biodiversity Management Committees (BMC) in India are women and every BMC is part of local government, therefore the same would be involved in Biosafety and promote gender equality and the empowerment of women adequate.

Private Sector Engagement

Is the case made for private sector engagement consistent with the proposed approach?

Secretariat Comment at PIF/Work Program Inclusion

December 14, 2021 HF:

Comment cleared. Please further develop this essential dimension of this project during PPG.

April 2, 2021 HF:

Please explain whether and how the project intends to engage the private sector.

Agency Response

December 7, 2021

The private sector will be engaged mainly through product developments and experience sharing on commodity management post approval including how they have been using new information to assist in development of regulatory packages, testing and monitoring of LMOs. The project intends to collaborate with private sector and work closely in the handling and management of non agriculture biotechnology products including animal vaccines, food and feed with LMOs.

Risks to Achieving Project Objectives

Does the project/program consider potential major risks, including the consequences of climate change, that might prevent the project objectives from being achieved or may be resulting from project/program implementation, and propose measures that address these risks to be further developed during the project design?

Secretariat Comment at PIF/Work Program Inclusion

April 2, 2021 HF:

Yes

Agency Response

Coordination

Is the institutional arrangement for project/program coordination including management, monitoring and evaluation outlined? Is there a description of possible coordination with relevant GEF-financed projects/programs and other bilateral/multilateral initiatives in the project/program area?

Secretariat Comment at PIF/Work Program Inclusion

April 2, 2021 HF:

Yes

Agency Response

Consistency with National Priorities

Has the project/program cited alignment with any of the recipient country?s national strategies and plans or reports and assessments under relevant conventions?

Secretariat Comment at PIF/Work Program Inclusion

April 2, 2021 HF:

Yes

Agency Response

Knowledge Management

Is the proposed ?knowledge management (KM) approach? in line with GEF requirements to foster learning and sharing from relevant projects/programs, initiatives and evaluations; and contribute to the project?s/program?s overall impact and sustainability?

Secretariat Comment at PIF/Work Program Inclusion

April 2, 2021 HF:

Yes

Agency Response

Environmental and Social Safeguard (ESS)

Are environmental and social risks, impacts and management measures adequately documented at this stage and consistent with requirements set out in SD/PL/03?

Secretariat Comment at PIF/Work Program Inclusion

April 2, 2021 HF:

Yes

Agency Response

Part III ? Country Endorsements

Has the project/program been endorsed by the country?s GEF Operational Focal Point and has the name and position been checked against the GEF data base?

Secretariat Comment at PIF/Work Program Inclusion

April 2, 2021 HF:

Yes

Agency Response

Termsheet, reflow table and agency capacity in NGI Projects

Does the project provide sufficient detail in Annex A (indicative termsheet) to take a decision on the following selection criteria: co-financing ratios, financial terms and conditions, and financial additionality? If not, please provide comments. Does the project provide a detailed reflow table in Annex B to assess the project capacity of generating reflows? If not, please provide comments. After reading the questionnaire in Annex C, is the Partner Agency eligible to administer concessional finance? If not, please provide comments.

Secretariat Comment at PIF/Work Program Inclusion

NA

Agency Response

GEFSEC DECISION

RECOMMENDATION

Is the PIF/PFD recommended for technical clearance? Is the PPG (if requested) being recommended for clearance?

Secretariat Comment at PIF/Work Program Inclusion

June 9, 2022 HF:

Comment cleared.

April 21, 2022:

No, please more clearly outline the plans to assess/analyze gender issues during PPG to inform project development and resubmit.

April 14, 2022:

Yes.

December 14, 2021:

No, not yet. Please respond to remaining comments.

ADDITIONAL COMMENTS

Additional recommendations to be considered by Agency at the time of CEO endorsement/approval.

Secretariat Comment at PIF/Work Program Inclusion
December 14, 2021 HF:

1.) Please note that target setting for Core Indicator 4 will be set during PPG based on site selection per criteria.

2.) Private sector engagement will be more fully developed during PPG.

Review Dates

	PIF Review	Agency Response
First Review	**4/2/2021**	
Additional Review (as necessary)	**12/14/2021**	
Additional Review (as necessary)	**4/14/2022**	
Additional Review (as necessary)	**6/9/2022**	
Additional Review (as necessary)		

PIF Recommendation to CEO

Brief reasoning for recommendations to CEO for PIF Approval

This Medium Sized Project (MSP) titled: ***Mainstreaming of Biosafety and Institutional Capacity Building to strengthen effective implementation of Cartagena Protocol on Biosafety,*** is focused on strengthening the mandated institutions and mainstreaming biosafety in the relevant national policies and processes to support the effective implementation of the Cartagena Protocol on Biosafety by India.

It seeks to translate the current installed capacity from the Union to the State Level to facilitate and support regulatory measures/monitoring mechanisms in relation to release of current, new and emerging LMOs into the marketplace and deliberate use in the environment. It will also ensure the implementation of a liability and redress regime guided by the supplementary protocol on Liability and Redress to ensure there is a robust administrative and operational system to support biosafety decision making in relation to deliberate release into the environment.

This is a $2,000,000 GEF and $10,775,000 co-finance project over 48 months with UNEP and the Indian Ministry of Environment, Forests and Climate Change. The project results include at least 6,000 beneficiaries.

The project has four components: 1. Stocking Assessment and Mainstreaming biosafety into policy and planning processes; 2. Regulations for new LMOs and emerging technologies; 3. Strengthening institutional capacity at Central and State levels; 4. Liability and redress; 5. Outreach and cooperation. The project activities will contribute to the Implementation of the Cartagena Protocol on Biosafety as outlined under Focal Area Programming Direction BD 3-8. This will ensure tools, interventions and capacity is installed to support science-based decision making in the sustainable utilization of biodiversity through modern biotechnology. The results and deliverables shall contribute to Aichi Targets 13 and 14 through safeguarding biodiversity, managing genetic resources and related benefits through sound science risk assessment, pre- and post-approval monitoring measures and engagement with the end users of genetic resources at the Central and State Levels.