IDB Inter-American Development Bank

REQUEST FOR EXPRESSIONS OF INTEREST
CONSULTING SERVICES

Selection: # RG-T3431-P001
Selection Method: Competitive Selection
Country: Argentina, Bolivia, Brazil, Chile, Colombia, Honduras, Mexico, Paraguay, Peru, and Uruguay.
Sector: Agriculture and Natural Resources
Funding – TC #: ATN/OC-17516-RG
Project #: *RG-T3431*
TC name: *Assessment of the Regulatory and Institutional Framework for Gene-editing via CRISPR-based Technologies in Latin America and the Caribbean*
Description of Services: The objective of this Consultancy will be to complete a targeted review of current agricultural biotechnology policies and trends, next-generation biotechnology methods with agricultural applications and the licensing structures surrounding them, and critically examine the challenges, opportunities and potential consequences of policy reform pathways which explicitly address next-generation gene editing processes and resulting end-products. Guidance document outputs will also provide the Bank with updates on key regional achievements and capacity deficits in next-generation biotechnology research and development and recommend opportunities for investment in human and physical resources accordingly.

Link to TC document: https://www.iadb.org/en/project/RG-T3431

The Inter-American Development Bank (IDB) is executing the above-mentioned operation. For this operation, the IDB intends to contract consulting services described in this Request for Expressions of Interest. Expressions of interest must be delivered using the IDB Portal for Bank Executed Operations (http://beo-procurement.iadb.org/home) by: *October 29th, 2019*, 5:00 P.M. (Washington D.C. Time).

The consulting services ("the Services") include:

Consulting Services	Description
Act. 1: Detailing current LAC & International regulatory structures	Literature review, document gathering, and key informant interviews to establish the baseline policy environment
Act. 2: Outline current CRISPR licensing landscape and protocols in agriculture	Licenser consultation, review of legal documentation, and discussion with key informants to elucidate necessary processes
Act. 3: Identifying trends and tendencies in gene editing among trade partners and international bodies	Lit. Review, Document Gathering, and Key informant interviews with relevant agencies to provide LAC clients with key market and policy intelligence
Act. 4: Elaboration of gene editing characteristics and uncertainties impacting regulatory decisions	Interviews conducted with diverse policy backgrounds, with synthesis and findings elaborated by country.
Act. 5: Identification of capacity for research and evaluation and Bank investment recommendations	Identification of diverse crop-country cases, qualitative and quantitative data collection, and scenario analysis under varying policies
Act. 6: Synthesis of findings and identification of capacity constraints for research and evaluation	Synthesizing and drawing lessons from Component 1 & 2 findings, interviews with key public and private sectoral actors to identify accomplishments and constraints.
Act. 7: Elaboration of investment strategy	Development of an investment strategy for agricultural biotechnology
Act. 8: Construction of written final outputs from Components 1-3	Finalization of findings in report chapters and tailored policy briefs

Act. 9 Construction and website content and policy briefs for Comp. 1-3 outputs	Iterative updating of an IDB-hosted website portal to facilitate timely access to TC results; ≥2 policy briefs for each Comp 1-3.
Act. 10: Media Analytics Workshop Dissemination	Pre-launch kick-off orientation, interim stakeholder workshop to present results from Comp.1 and 2, and a regional workshop to present complete results.

Eligible consulting firms will be selected in accordance with the procedures set out in the Inter-American Development Bank: *Policy for the Selection and Contracting of Consulting firms for Bank-executed Operational Work* - GN-2765-1. All eligible consulting firms, as defined in the Policy may express an interest. If the Consulting Firm is presented in a Consortium, it will designate one of them as a representative, and the latter will be responsible for the communications, the registration in the portal and for submitting the corresponding documents.

The IDB now invites eligible consulting firms to indicate their interest in providing the services described below in the draft summary of the intended Terms of Reference for the assignment. Interested consulting firms must provide information establishing that they are qualified to perform the Services (brochures, description of similar assignments, experience in similar conditions, availability of appropriate skills among staff, etc.). Eligible consulting firms may associate in a form of a Joint Venture or a sub-consultancy agreement to enhance their qualifications. Such association or Joint Venture shall appoint one of the firms as the representative.

Interested eligible consulting firms may obtain further information during office hours, 09:00 AM to 05:00 PM, (Washington D.C. Time) by sending an email to: *Eirivelthon Lima (elima@iadb.org).*

Inter-American Development Bank
Division: ENVIRONMENT, RURAL DEVELOPMENT AND DISASTER RISK MANAGEMENT DIVISION
Attn: Eirivelthon Lima, Program Team Leader

Avenida 6 de Agosto No. 2818, Zona San Jorge, La Paz, Bolivia
Tel: *+591 2 217 7720*
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Selection process #: RG-T3431-P001

DRAFT TERMS OF REFERENCE

Consultancy for Advising Agricultural Gene Editing Policy Reform Pathways in the LAC Region

Latin America and Caribbean (LAC) REGIONAL:
Argentina, Brasil, Uruguay, Paraguay, Bolivia, Colombia, Perú, México, and Honduras

RG-T3431
"Assessment of the Regulatory and Institutional Framework for Agricultural Gene-editing via CRISPR-based Technologies in Latin America and the Caribbean"

1. Background and Justification

1.1. Breakthroughs in biotechnology, namely optimization of gene-editing via CRISPR-based technologies, have facilitated remarkable gains in precision, speed and cost-effectiveness of genome modification in agriculture (Shan et al., 2013). Developers have widely claimed innovative gene-editing technologies can significantly increase the pace of crop and livestock genetic improvement to meet increasing productivity demands and future environmental challenges (Gao, 2018). CRISPR-Cas9 technology could be a major disrupter in Latin American and Caribbean (LAC) agricultural development through varietal improvement, tackling low productivity and providing a vehicle to expedite crop adaptation to climate change. As Science magazine's 2015 'Breakthrough of the Year', CRISPR's potential impact simply cannot be ignored by any agricultural development institution.

1.2. While gene-editing is not new, innovative tools are revolutionizing the field. CRISPR technology works as a 'search and replace' method that scans DNA and guides a protein such as Cas9 to cut at a specific target sequence. The resulting repair at the site can be designed to insert, alter, or simply remove (i.e. 'knock-out') portions of DNA to achieve some physical trait change. For example, Cornell's Alliance for Science highlights CRISPR use by researchers at Argentina's Instituto Nacional de Tecnología Agropecuaria to turn off a key gene that causes browning in potatoes. Researchers at the Centro Internacional de Agricultura Tropical have also used CRISPR to perform edits in rice and beans to resist disease and improve digestibility (Norero, 2018). CRISPR licensing with private and public entities is expanding gene-editing in global agriculture (Guerrini et al., 2017).

1.3. First-generation GMO crops are transgenic end products containing foreign DNA, leading to the catch-all GMO colloquialism 'transgénicos'. But gene-editing can produce organisms which are genetically edited but contain no transgenes. This changes key legal descriptive terminology and may alter risk perceptions among regulators and the public. If accepted as 'safer', lower development costs coupled with regulatory hurdles could allow greater non-profit institutional involvement. This could lead to targeting more diverse crops and traits prioritized by the poor, while also speeding innovation and dissemination. However, public confidence challenges may lead to conclusions that the social cost of reducing regulatory burden outweighs the opportunity costs of lost potential value to farmers and consumers.

1.4. The future of regulatory oversight of gene-edited products is particularly ambiguous throughout much of the LAC region, given key distinctions in the gene-editing process and composition of edited organisms compared to first-generation genetically modified organisms (GMOs). Guidance on the economic, political, and social ramifications of LAC national policy decisions is both critically needed and timely, given the immense potential of the technology and widespread desire to avoid tensions created with first-generation GMOs in agriculture.

Most LAC countries have not yet ruled on regulatory paths or updated risk assessment pathways for gene-edited organisms. While eleven LAC countries have some legal status for first-generation GMO crops (ISAAA, 2017), the existing GMO regulatory heterogeneity points to diverse pathways forward with gene-editing.

1.5. Among the few addressing it directly, Argentina (2015, via NR 173/2015) and Brazil (2018, via NR 16) will evaluate gene-edited products on a case-by-case basis and give regulatory exemption where there is no insertion of transgenes. In the background, the UN Convention on Biological Diversity (CBD) Conference of the Parties (COP) convened in Egypt in 2018 and deliberated on gene-editing and "living organisms developed through synthetic biology"(CBD, 2017). Historically, LAC countries have widely adopted terminology and governance of biotechnologies based on the Cartagena Protocol, so the UN CBD meeting and eventual guidance is highly consequential for the region. Thus, the TC timeline is also timely to guide translation of CBD COP meeting outcomes into potentially highly consequential policies. It is imperative to present a full array of ramifications of each path forward, considering governmental, academic, and private breeding programs, domestic large and small growers, consumers, and social trust.

1.6. Regulators in the US and EU have taken sharply different approaches to gene-editing oversight, with major potential consequences for competitiveness and trade trajectories. The US has determined that gene-edited organisms which do not pose a plant pest risk, have no traces of DNA from distant species, and which could arise spontaneously or from conventional mutagenesis, will not be regulated further (Waltz, 2016). However, the EU Court of Justice (ECJ) ruled that gene-edited products would be regulated like first-generation GMOs (Stokstad, 2018). This decision was criticized by many in Europe's biotechnology industry and research community but lauded by some environmental groups (ibid). The ECJ contended that although gene-editing alteration "does not occur naturally" and poses "similar" risks to transgenic methods. Researchers have found incongruent GMO policies negatively impact Southern Cone exports of key first-generation GMO crops, so lack of harmonization in next-generation biotechnologies may continue hindering regional trade (Smith and Katovich, 2016).

1.7. Biotechnology developers have called for a science-based regulatory approach which accommodates increased precision of CRISPR methods (Barrangou, 2018; Stokstad, 2018). This was echoed in WTO statements by Argentina, Brazil, Guatemala, Honduras, Paraguay, and the USA, among others (WTO, 2018). But prominent scholars have argued the importance of public trust and that the complexity in gene-editing terminology and differences between methods are inevitably confusing and "could be a significant barrier to informed decision-making about [GMO] crops and foods" among citizenry (Kuzma, 2018). Experts also note the public's "interpretive flexibility" considering gene-edited products as 'GMOs' and non-science-based factors arising in policy making (Duensing et al., 2018).

1.8. For this regional study, during TC preparation we have designated the following target countries: Argentina, Bolivia, Brazil, Colombia, Honduras, Mexico, Paraguay, Peru, and Uruguay. These countries were incorporated through the following selection criteria: regional diversity, diverse engagement with first-generation biotechnology, diversity in research and evaluation capacity levels, and diversity in engagement with next-generation gene editing regulations. Argentina and Brazil represent large Southern Cone economies with proactive gene editing regulations from which regional lessons could be drawn. Paraguay and Uruguay represent smaller Southern Cone economies with wide planting of biotech crops, though Paraguay has more developed explicit gene editing policies. Bolivia and Colombia represent Andean economies with limited biotech crop approval, though only Colombia has begun to explicitly address gene editing in regulatory updates. Peru represents in Andean economy with no previous biotech crop experience and the end of their biotech moratorium provides an opportunity to address gene editing within ongoing reforms. Mexico and

Honduras represent North and Central American economies with varying levels of capacity and restrictions on biotech crop planting, both with no clear direction on how gene editing may be addressed.

1.9. The main issues to be studied under the consultancy are: (i) Current Policy Evaluation: including existing agricultural biotechnology policies and cost/time necessary to bring a product to market in identified regional states, policy trends and tendencies of select major trading partners (USA, EU, China, Japan) and international bodies (e.g. United Nations Convention on Biological Diversity), gaps in identified regional state policies to address process and end-product distinctions with next-generation gene editing methods, and the current CRISPR licensing structures for private firms and non-profit/governmental bodies seeking to eventually translate R&D output for commercialization; (ii) Forecasting and Future Policy Scenario Analysis: including targeted crop-country case study examples with emerging next-generation biotechnology products to illustrate economic, trade, and social consequences of potential policy directions; (iii) Identifying Bank investment priorities: including documentation of regional gene editing product developments, key capacity deficits, and future opportunities for Bank investment in human and physical capital.

2. Objectives

2.1. The objective of this Consultancy will be to complete a targeted review of current agricultural biotechnology policies and trends, next-generation biotechnology methods with agricultural applications and the licensing structures surrounding them, and critically examine the challenges, opportunities and potential consequences of policy reform pathways which explicitly address next-generation gene editing processes and resulting end-products. Guidance document outputs will also provide the Bank with updates on key regional achievements and capacity deficits in next-generation biotechnology research and development and recommend opportunities for an investment strategy for the region.

3. Scope of Services

START-UP PHASE

3.1. Establishing an Integrated Governance Structure. It is important to establish at the very beginning of the project an integrated governance structure combining the key stakeholders from the participating countries, the IDB, and the consultant team. During the start-up phase, the consulting institution will propose a governance structure in order to work with the key stakeholders and the IDB to establish the project work plan, processes, and tools the consulting institution will use to plan, execute, monitor, control and report project activities. The work plan should include a loose structure of an IDB-hosted website portal to host key project results, and a plan to update with content as results are generated. The consultancy team will also propose a coordination and collaboration strategy with the hired Individual Consultant for the remainder of project activities.

3.2. Establishing project management methodology. It is required that bidders produce a project management methodology. Bidders should include their proposed approach for communication management, quality management, risk management, and oversight and monitoring.

3.3. Kick-off meetings. It is important at the start of a project with many components and stakeholders, such as those proposed in this ToR, to develop a common understanding of the project's scope, objectives and clear deliverables expectations and establish a consistent approach to executing the project work and reporting on project progress. To begin our collaborative journey towards an on-time, within-budget, and quality deliverables implementation that meets the IDB's and stakeholders' expectations, the consulting institution should work with the IDB and key stakeholders to schedule and conduct a formal Kick-Off Meeting. This meeting will likely be located, tentatively, in Panama City, Panama. The associated budget for execution (aside from travel of consultancy team representatives) will be handled be the Bank.

EXECUTION PHASE

3.4. Implications of Regulatory Developments for LAC Agricultural Biotechnology Policy. The consultant team

will begin with a review of current literature and relevant agricultural biotechnology policies, institutional frameworks and responsibilities in identified countries (Argentina, Brazil, Uruguay, Paraguay, Bolivia, Colombia, Peru, Mexico, and Honduras) and will as engage with relevant national agencies and technology licensing bodies to (i) Assess the baseline agricultural biotechnology legal framework of the participating LAC countries, (ii) detail institutional arrangements for production and regulation of agricultural biotechnologies, including [where available] the steps, costs, and timeline from application to approval of commercial products, (iii) outline the implications of baseline international agreements (e.g. Cartagena Protocol on Biosafety) relevant for biotechnology and gene editing. (iv) Detail limited LAC regional gene-editing resolution updates in place or under active consideration (v) Detail the protocol for the current CRISPR licensing landscape, specifically the licensing procedures necessary for LAC SMEs, as well as clarifying the steps by which developments from non-profit LAC institution using CRISPR intellectual property suites may reasonably lead to commercial products. (vi) Map current agricultural biotechnology regulatory trends and tendencies from non-regional trade partners such as USA, EU, Japan, and China and the implications for baseline LAC frameworks (vii) Review major policy tendencies in the international arena (e.g. the UN CBD 2018 meeting) to help countries understand the evolving international policy environment. (viii) Based on trends/reforms identified, provide anticipatory policy recommendations to improve regulatory and institutional frameworks in LAC, with particular emphasis on trade implications.

3.5. Influence of Gene-Editing Characteristics on Future Policy Direction and Scenario Analysis of Country-Crop Gene-Editing Case Studies. Considering findings from baseline policy reviews, the team will conduct in-depth key informant interviews for at least four identified LAC regional states (including at least one state in each cluster: Argentina, Brazil, Paraguay, Uruguay; Bolivia, Colombia, and Peru; Mexico and Honduras), drawing from biotechnology developers, private and public breeders, relevant policymakers, and consumer groups and NGOs. Key informant interviews will serve to evaluate (i) which gene-edited agricultural products, with which attributes, would likely still be covered by current regulations, (ii) which products, with which attributes, may be able to meet less stringent regulations, (iii) identify key concerns and uncertainties about gene editing technologies and characteristics which may impact regulatory updates in relevant countries, (iv) Identify and detail case studies of at least two (2) emerging or prospective gene-edited crop or livestock varieties, in at least (2) countries with diverse existing policies, to conduct economic and policy scenario analysis to provide tangible illustrations of the consequences of various potential policy directions. This will be executed utilizing field study with key informant interviews and relevant (likely secondary) data to provide decision makers with key qualitative and, to the extent possible, quantitative analysis of economic, trade, and social consequences of various regulatory pathways which are tailored to specific country contexts.

3.6. Agricultural Biotechnology Investment Strategy. The consultant team will then (i) synthesize major findings from the previous components, considering baseline policy environments and tendencies, key specific country- and regional-level concerns about gene-editing technical and policy constraints. Team experts will then (ii) highlight and categorize major gene-editing developments by LAC entities from the public sector, SMEs, and large LAC-based private entities, (iii) review of the agriculture innovation projects financed by the bank in the past 10 years; (iv) interview with project team leaders of the Bank and other Multilateral Development Banks (MDBs) to understand constraints and limitations to design projects that incorporate the latest biotechnology discoveries; and (iii) identify the key capacity deficits in research, development, evaluation, regulatory, and policy formulation surrounding next-generation biotechnology and (iv) propose specific avenues for Bank investments in both human and physical capital.

3.7. Draft Final Report and Stand-Alone Report Identifying Bank Investment Priorities in Agricultural Biotechnology. Upon full completion of the desk study, field studies, expert and key informant interviews, the consulting team will prepare a cohesive Final Report, divided into complementary chapters which detail all component findings. The Draft Final Report will also detail the illustrative quantitative (as available) and

qualitative country-crop case studies to provide policymakers with tangible examples of positive and negative consequences of specific reform pathways. A synthesis of project findings and explicit recommendations for Bank investments in next-generation agricultural biotechnology will be included within the Draft Final Report, but also function as a stand-alone document for policymakers and Bank use.

4. Main Activities

4.1. A summary of the main activities of the consultancy include, but are not limited to:

Product Themes	Description of Main Activities
	Start-up
• Governance structure for Project Management • Work Plan	Act.1: Design governance structure for the execution of the consultancy. Act.2: Participate in Kick-off meeting to validate the work plan
	Execution
• LAC Regulatory Structure • International Regulatory Trends and Tendencies • CRISPR Licensing Landscape and Procedures • Impacts of Gene Editing Characteristics on Regulatory Decision • Case Study Examples	The consultant will take on an in-depth review of the literature, national and international policy documents, key informant interviews, and consultations with relevant national agencies and CRISPR licensing bodies to: Act.1: Detail current LAC & International regulatory structures Act.2: Outline current CRISPR licensing landscape and protocols in agriculture Act.3: Identify trends and tendencies in gene editing among trade partners and international bodies Act.4: Elaborate specific gene editing characteristics and uncertainties impacting regulatory decisions Act.5: Conduct a targeted case study investigation for future policy scenario analysis
	Synthesis and Elaboration of Agricultural Biotechnology Investment Priorities
• Findings synthesis • Outlining of specific Bank investment recommendations	Field experts will then: Act.1: Synthesize and draw lessons from previous findings and undertake field visits and interviews with key public and private sectoral actors to identify LAC accomplishments and capacity constraints in the evaluation, research, and development of agricultural gene editing. Act.2: Create a ranked priority list for Bank investment in human and physical capital at the country and regional level.
	Dissemination
• Written Materials • Workshops	Throughout the execution of the project, the consultant will provide progress updates and reports, culminating with a final report with complementary chapters on each product theme through:

	Act.1: Iterative written reports including a Preliminary Report, two Interim Reports, a Final Report and associated short policy briefs, and a stand-alone report on Back investments in the sector, with active engagement from stakeholders, following the timeline elaborated below. Act.2: A smaller progress workshop for key stakeholders to present initial findings and a larger stakeholder workshop once final results are established, following the timeline elaborated below.

5. Qualifications of the Consultant Firm

5.1. To complete the services of the consultancy, a Firm or, preferably, a consortium structure is sought which meets the following requirements:

General Experience:

(a) A minimum of 8 years of handling contracts or grants;

(b) A minimum of 8 years of focus on genetic engineering topics in agriculture

Specific Experience:

(c) Documented interdisciplinary publication record in academic journals between firm associates and affiliates across the natural and social sciences;

(d) Latin American regional experience among firm associates, affiliates, and/or specialists;

(e) Evidence of hosting events on genetic engineering topics in agriculture at an international scale;

(f) Evidence of large-scale policy reviews in genetic engineering topics in agriculture;

Qualifications of Key Professional Personnel of the Consultancy Institution

5.2. Beyond firm-level requirements, the consultancy firm should contain a minimum multidisciplinary team of (6) professional directly in charge of executing project activities and deliverables described in this Terms of Reference.

5.3. Minimum profiles of key personnel shall include:

Function	Quantity	Academic Credentials	Experience
Consultancy Team Lead	1	Master's degree with preference for Ph.D. in Biotechnology-related field, or in a Social Science or Applied Economics field with biotechnology training and/or research-focus	General: 6. Minimum of 10 years of professional experience Specific: 7. Evidence of interdisciplinary collaboration and transdisciplinary research output, 8. Demonstrated biotechnology and policy literacy 9. Demonstrated understanding of economic and social issues surrounding biotechnology, 10. LAC regional experience preferred 11. English and Spanish and/or Portuguese proficiency preferred.
Biotechnologist	1	Ph.D. in Biotechnology-related field	General: • Minimum of 10 years of professional experience Specific: • Evidence of successful interdisciplinary collaboration, especially with the social sciences. • Experience in biotechnology policy preferred. • LAC regional experience preferred • English and Spanish and/or Portuguese proficiency preferred.
International Biotechnology Law Expert	1	J.D.	General: • Minimum of 7 years of professional experience Specific: • Collaborative research experience related to biotechnology policy. • Experience on review of licensing agreements in the field of biotechnology applied to agriculture.

Applied Economist	1	Ph.D. in an applied economics field	General: • Minimum 10 years of professional experience Specific: • Biotechnology policy research focus • Evidence of interdisciplinary collaboration • LAC regional experience preferred • English and Spanish and/or Portuguese proficiency preferred.
Social Scientist	1	Master's or Ph.D. in a social science field such as public policy, public administration, sociology, or anthropology	General: • Minimum 10 years of professional experience Specific: • Significant experience in international biotechnology policy and surrounding socio-economic issues • Evidence of interdisciplinary research or collaborative experience • LAC regional literacy or experience preferred • English and Spanish and/or Portuguese proficiency preferred.
Communications Specialist	1	Bachelor's Degree	General: • Minimum 5 years of professional experience Specific: • Experienced individual in public and preferably science communications to support, e.g., the adaptation of project reports to policy briefs and website content, as well as other public and stakeholder-facing outputs • English and Spanish and/or Portuguese proficiency preferred.

6 Expected Outcome and Deliverables

6.1. The consultant will present the following products:

Product #1 - Preliminary Report:

- **Product 1.1**. Preliminary Report composed of a draft baseline policy and institutional review for identified LAC regional states, an analysis of trends and tendencies in non-regional major trading

partners and international institutional agreements, and an informative synopsis of next-generation agricultural biotechnologies and their current and potential application to regional agriculture, and a clear illustration of described CRISPR licensing structures and procedures. For quality control and increased buy-in, a working group with several representatives from each beneficiary region (Mexico & C.A., Andean Community, Southern Cone) will also be identified from relevant agencies to preview TC outputs and provide feedback.

- **Product 1.2**. Two short policy briefs adapted from LAC baseline and gene-editing regulatory updates and international trends and tendencies, and/or CRISPR licensing.
- **Product 1.3**. Written website content summarizing major Preliminary Report findings. Both briefs and website content are to be submitted within one month after the Preliminary Report.

Product #2 – First Interim Report:

- **Product 2.1**. The main written deliverable from this component, drawn from information gathered during field visits and key informant interviews, will be a First Interim Report that builds from the analysis of the baseline policy environment findings. This Interim Report is expected to extensively cover (4.6.4) items (i),(ii), and (iii) and provide an update of progress and initial findings for item (iv).
- **Product 2.2**. Two short policy briefs adapted from key First Interim Report findings. Written website content summarizing major First Interim Report findings. Both briefs and website content are to be submitted in conjunction with the First Interim Report.
- **Product 2.3**. After the Preliminary Report and First Interim Report products are delivered and accepted, representatives from the consultant(s) will travel, likely to Panama City, Panama, to present findings of the 'Implications of Regulatory Developments for LAC Agricultural Biotechnology Policy.' progress and initial insights on the 'Influence of Gene-Editing Characteristics on Future Policy Direction and Scenario Analysis Of Country-Crop Gene-Editing Case Studies. Note that the event organization itself, and associated budget for execution (aside from travel of consultancy team representatives), will be handled be the Bank. The workshop audience will be composed of identified regional policymakers, national agency staff, and other relevant and interested parties.

Product #3: Second Interim Report.

- **Product 3**.1 The team, as necessary, will then continue data collection and analysis building on previous findings. The team will expand scenario analysis of country-crop case studies, utilizing, e.g., expert elicitations, key informant interviews, and other relevant quantitative data for analysis. A Second Interim Report will detail and synthesize further findings as well as greater detail of the results of case study evaluations.
- **Product 2.2**. Two short policy briefs adapted from key Second Interim Report findings. Written website content summarizing major Second Interim Report findings. Both briefs and website content are to be submitted in conjunction with the Second Interim Report.

Product #4: Agriculture Biotechnology Investment Strategy

- **Product 4.1.** Team field experts will then identify the key capacity deficits in research, development, regulation, and policy formulation surrounding next-generation biotechnology and propose specific investment biotechnology strategy for the region.

Product #5: Final Report and Workshop

- **Product 5.1.** Final Report. Upon full completion of the desk study, field studies, expert and key informant interviews, the consulting team will prepare a cohesive Final Report, divided into complementary chapters which detail all component findings. The Draft Final Report will also detail the illustrative quantitative and qualitative country-crop case studies to provide policymakers with tangible examples

of positive and negative consequences of specific reform pathways. A synthesis of project findings and explicit recommendations for Bank investments in next-generation agricultural biotechnology will be included within the Draft Final Report.

- **Product 5.**2. Final Workshop. After the delivery of products 1 to 5, representatives from the consultant(s) will travel, likely to Panama City, Panama, to present findings of the 'Implications of Regulatory Developments for LAC Agricultural Biotechnology Policy.' progress and initial insights on the 'Influence of Gene-Editing Characteristics on Future Policy Direction and Scenario Analysis Of Country-Crop Gene-Editing Case Studies. Note that the event organization itself, and associated budget for execution (aside from travel of consultancy team representatives), will be handled be the Bank. The workshop audience will be composed of identified regional policymakers, national agency staff, and other relevant and interested parties.

7 General Project Schedule and Milestones

Activities	Maximum Date of Submission After Signing of the Contract*
Construction of Work plan, governance structure, project management devised	0-30 days
Kick-off meeting	60 days
Baseline LAC GMO & Gene-editing regulation summary	60-180 days
Major international trading partner (USA, EU, China) biotech reg. trends	60-180 days
CRISPR licensing protocols, environment	60-180 days
Synthesizing UN CBD meeting output related to gene-editing in agriculture	60-180 days
Product 1: Preliminary Report, Policy Briefs, and Website content submission	180 days
Regional gene-edited product development and capacity summary	150-240 days
Expert Elicitation to build list of key gene-editing application characteristics	150-300 days
Case study candidates identified, preliminary data collection and analysis	210-300 days
Product 2: First Interim, Policy Briefs, Website content submission	300 days
Product 2: First findings workshop presentation	300 days
Case study expansion and detailed case data gathering based on candidates identified	270-390 days
Product 3: Second Interim Report submission	390 days
Review of LAC, US, EU, China policy reforms through course of project, updates/revisions where necessary	300-450 days
Synthesis, identification of key capacity constraints, recommendations for Bank investment	390-450 days
Final report authoring	420-480 days
Product 4: Submission of Draft Final Report, Policy Briefs, Website Content, Stand-alone Report on Recommendations for Strategic Bank Investments	480 days
Product 4: Final findings presentation	510 days
Final report Bank/stakeholder review	480-570 days
Product 5: Submission of Final report, Website content finalization submission	570 days
Product 5: Final report review, potential revisions, and finalization	570-600 days

Activities	Maximum Date of Submission After Signing of the Contract*
Product 5: Academic Journal Article Submission(s)	600 days
Final report dissemination	600-660 days

*Note: All submitted materials will entail a 10-day Bank review period and a 10-day consultant reaction period.

8 Reporting Requirements

8.1. Specific description of the reports consulting firm will have to submit for each phase of the project. For example: the scope and timing of progress reports; the need for presentations/ workshops; the coverage and timing of reports, setting out the results of the consultancy.

Deliverable Milestones	Description	Maximum Date of Submission After Signing of the Contract*
Work plan, governance structure, project management plan devised & submitted	Detailed Plan and schedule of the consultancy, proposed governance, and management plan	30 days
Kick-off meeting workshop	Engagement with key stakeholders to finalize workplan	60 days
Product 1: Website content submission	Detailed Product 1 website material	180 days
Product 1: Policy Briefs submission	Two targeted policy briefs on key Product 1 findings	180 days
Product 1: Preliminary Report submission	Baseline LAC policy environment, Implications of International Regulatory Developments for LAC Agricultural Biotechnology Policy, and state of CRISPR licensing	180 days
Product 2: Website content submission	Detailed update with Product 2 website material	300 days
Product 2: Policy Briefs submission	Two targeted policy briefs on key Product 2 findings	300 days
Product 2: First Interim Report	Key Informant Interviews, Expert Elicitation, Case Study Identification	300 days
Product 2: First findings workshop presentation	Preliminary Report and First Interim Report results	300 days
Product 3: Second Interim Report submission	Elicitation and Case Study Continuation	390 days
Product 4: Website Content submission	Detailed update with Product 3 website material	480 days
Product 4: Policy Briefs submission	Two targeted policy briefs on key Product 3 findings	480 days
Product 4: Draft Final Report Submission	Complementary chapters which detail all component findings	480 days
Product 4: Stand-alone Bank investment strategic recommendation Report Submission	Synthesis and explicit recommendations for Bank investments	480 days
Product 4: Final findings workshop presentation	Final findings presentation	510 days
Product 5: Website content finalization submission	Detailed update with finalized website material	570 days
Product 5: Final report Submission	Complementary chapters which detail all component findings	570 days
Product 5: Final report review, potential revisions, and finalization	Potential last corrections to final documents	600 days
Product 5: Academic Journal Article Submission(s)	Maximum length before documented submission of at least one academic article from project	600 days

*Note: All submitted materials will entail a 10-day Bank review period and a 10-day consultant reaction period.

8.2. Language of submitted deliverables:

1. The language of the Preliminary, First Interim, & Second Interim reports may be delivered in **English**.
2. Each Policy Brief will be delivered with **English and Spanish** versions.
3. Website content submission will be delivered with **English and Spanish** versions.
4. The Final Report and Report on Recommended Strategic Bank Investments will be delivered with **English, Spanish, and Portuguese** versions.

9 Acceptance Criteria

9.1 Product Management Process. To ensure alignment of expectations between the consultant, IDB, and beneficiary countries, the following process will be followed for the delivery of major written deliverable products:

- Consultant develops Product Expectation Document;
- Joint review and approval of Product Expectation Document;
- Consultant develops product;
- Joint review and refinement walk-through of document;
- Consultant submits product;
- Bank reviews submission;
- Bank issues acceptance letter;
- Consultant submits invoice for product.

9.2 IDB Project Leads Eirivelthon Santos Lima (elima@iadb.org) and/or Gonzalo P. Muñoz (gonzalom@iadb.org) are authorized to ultimately accept the work.

10 Other Requirements

10.1 No special requirements, such as security requirements, any IT access restrictions/requirements or system downtime/maintenance are anticipated.

11 Supervision and Reporting

11.1 The consulting firm will report to IDB Project Leads Eirivelthon Santos Lima and Gonzalo P. Munoz. Communication will follow, at a minimum, at a rate acceptable to coordinate the commenting and approval process detailed in the (8.1) Project Management Process. The consulting firm will also work in close collaboration with the hired Individual Consultants, conducting, at a minimum, weekly written and/or phone updates to verify progress.

12 Schedule of Payments

12.1 Payment terms will be based on project milestones or deliverables. The Bank does not expect to make advance payments under consulting contracts unless a significant amount of travel is required. The Bank wishes to receive the most competitive cost proposal for the services described herein.

12.2 The IDB Official Exchange Rate indicated in the RFP will be applied for necessary conversions of local currency payments.

Payment Schedule	
Deliverable	**%**
1. Upon signature of the contract and delivery of an updated workplan (activities and products delivery date).	30%
2. Upon presentation and approval of Product 1.	20%

3. Upon presentation and approval of written components of Product 2.	10%
4. Upon presentation and approval of written components of Product 3 and participation in First Findings Presentation.	10%
5. Upon presentation and approval of written products of Products 4 and 5 and participation in Final Findings Presentation.	30%
TOTAL	100%