

TC ABSTRACT

I. Basic Project Data

▪ Country/Region:	REGIONAL/IDB
▪ TC Name:	Assessment of the Regulatory and Institutional framework for gene-editing via CRISPR-based technologies in Latin America and the Caribbean
▪ TC Number:	RG-T3431
▪ Team Leader/Members:	LIMA, EIRIVELTHON SANTOS (CSD/RND) Team Leader; MUNOZ, GONZALO P. (CSD/RND) Alternate Team Leader; MILEWSKI, JOSEPH CHRISTOFER (CSD/RND); MATTOS, JUAN DE DIOS (CSD/RND); BUSTAMANTE, CESAR TULIO (CSD/RND); VALLE PORRUA, YOLANDA (CSD/CSD); GRUNWALDT, ALFRED HANS (CSD/CCS); BALCAZAR V., FERNANDO (CSD/RND); DAMIANI MARTI, OCTAVIO JORGE (CSD/RND); RIOS GALVEZ, ANA R. (CSD/RND); ANTA, RAFAEL (IFD/CTI); CATALANO, FERNANDO DAVID
▪ Taxonomy:	Research and Dissemination
▪ Number and name of operation supported by the TC:	N/A
▪ Date of TC Abstract:	11 Feb 2019
▪ Beneficiary:	Farmers and consumers across the Latin America and the Caribbean (LAC)
▪ Executing Agency:	INTER-AMERICAN DEVELOPMENT BANK
▪ IDB funding requested:	\$ 600,000.00
▪ Local counterpart funding:	\$ 0.00
▪ Disbursement period:	30 months
▪ Types of consultants:	Individuals; Firms
▪ Prepared by Unit:	Env, Rural Dev & Disaster Risk
▪ Unit of Disbursement Responsibility:	Country Office Bolivia
▪ TC included in Country Strategy (y/n):	Yes
▪ TC included in CPD (y/n):	No
▪ Alignment to the Update to the Institutional Strategy 2010-2020:	Productivity and innovation

II. Objective and Justification

- 2.1 The main objective of this TC is to provide guidance for national agencies of the countries members of the Bank responsible for biotechnology applied to the agriculture sector to bridge existing agricultural biotechnology policy to explicitly address gene-editing in regulatory development and/or updates. We will create the first specialized report on gene-editing in agriculture for the LAC region, outlining explicit roadmaps with decision break points to guide agencies considering the socio-economic, competitiveness, and trade implications of regulatory updates.
- 2.2 Breakthroughs in biotechnology, namely optimization of gene-editing via CRISPR-based technologies (short for clustered regularly interspaced short palindromic repeats), 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 technology could be a major disrupter in 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. Several gene editing techniques exist, but by far the most popular and versatile is the CRISPR method. The 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. And just six years after scientists published the first papers showing how CRISPR could work in plants and animals, it is sweeping through the world's academic and corporate laboratories. Some applications, such as more flavorful tomatoes and mushrooms that do not turn brown as they age or after they are cut – greatly extending shelf life and reducing waste – are closely to being commercialized in the US. Gene editing is faster, simpler and more accurate than conventional genetic modification and does not involve inserting a foreign gene into the DNA. This changes key legal descriptive terminology and may alter risk perceptions among regulators and the public. In the first-generation, Genetically Modified Organism (GMO) crops are transgenic end products containing foreign DNA. Gene editing supporters had hoped the distinction between gene editing and the older genetic modification (transgenic) would be accepted as 'safer', therefore, avoiding the regulatory scrutiny that has thwarted the rollout of GMO in the EU in particular. The gene editing lower development costs coupled with reduced costs of regulatory compliance could allow greater non-profit institutional involvement. This could lead to targeting of more diverse crops and novel traits prioritized by the poor, while also speeding innovation and producer dissemination. Finally, the CRISPR technology directly addresses lagging productivity through genetic improvement, while operating at the forefront of breeding innovation and presenting broad opportunity for North-South and South-South collaboration. However, the complex policy and social landscapes of the LAC region may lead some countries to reject or remain highly skeptical of gene-editing due to concerns about social exclusion, inequality, and beliefs about impacts on environmental sustainability.

III. Description of Activities and Outputs

- 3.1 Output 1: Report assessing the legal and institutional framework on biotechnology applied to agriculture. Activities: (i) develop the baseline agricultural biotechnology legal framework of LAC countries, (ii) assess country-specific institutional arrangements for production and regulation of agricultural biotechnologies, including [where available] the steps, costs, and timeline from application to approval of commercial products, and (iii) review the relevant baseline international agreements (e.g. Cartagena Protocol on Biosafety);
- 3.2 Output 2: Report assessing the implications of regulatory developments from the UN CBD, EU, USA, Japan and China for LAC agricultural biotechnology policy development. Activities: (i) map current regulatory trends and tendencies from major non-regional trade partners such as the USA, EU, Japan, and China in agricultural biotechnology and implications for baseline LAC frameworks identified in Component 1; and (ii) Provide anticipatory policy recommendations to improve regulatory and institutional frameworks in LAC, with particular emphasis on trade implications.
- 3.3 Output 3: Influence of Unique Characteristics of Gene-Editing Process and Products for Future Policy Direction, LAC capacity for gene-editing R&D, and potential Bank investment priorities. Activities: 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, and (iii) Identify major gene-editing developments by LAC entities and key capacity deficits, with potential avenues for Bank investments in human and physical capital.

- 3.4 Output 4: Breakout case studies of country-crop specific gene-editing applications under different regulatory scenarios. Activities: (i) Identify and detail case studies of potential gene-edited crop and livestock varieties to provide tangible and relevant illustrations of policy direction consequences.
- 3.5 Output 5: Dissemination. Activities: (i) Production of knowledge product that extensively details findings in Components 1-4, with accompanying self-contained chapters for each component; (ii) Publication of core findings in peer-reviewed policy journals as well as the Bank's knowledge repository and accompanying summary blog posts; and (iii) Construction of short policy briefs for national agencies
- 3.6 **Component I: Baseline LAC international and national agricultural biotechnology policies.** This component will assess the baseline of agricultural biotechnology legal and institutional framework of the Latin America and the Caribbean countries.
- 3.7 **Component II: Implications of Regulatory Developments from the UN CBD, EU, USA, Japan and China for LAC Agricultural Biotechnology Policy.** This component will map the current regulatory trends and tendencies from major non-regional trade partners such as the USA, EU, Japan, and China in agricultural biotechnology and implications trade.
- 3.8 **Component III: Influence of Unique Characteristics of Gene-Editing Process and Products for Future Policy Direction, LAC capacity for gene-editing R&D, and potential Bank investment priorities.** This component will undertake an assessment of regional capacity differences and recommendations for Bank capacity building investments
- 3.9 **Component IV: Breakout case studies of country-crop specific gene-editing applications under different regulatory scenarios.** Identify and detail case studies of potential gene-edited crop and livestock varieties to provide tangible and relevant illustrations of policy direction consequences.
- 3.10 **Component V: Public dissemination.** This component will finance the dissemination of the results of the TC.

IV. Budget

Indicative Budget

Activity/Component	IDB/Fund Funding	Counterpart Funding	Total Funding
Baseline LAC international and national agricultural biotechnology policies	\$ 180,000.00	\$ 0.00	\$ 180,000.00
Implications of Regulatory Developments from the UN CBD, EU, USA, Japan and China for LAC Agricultural Biotechnology Policy	\$ 120,000.00	\$ 0.00	\$ 120,000.00
Influence of Unique Characteristics of Gene-Editing Process and Products for Future Policy Direction, LAC capacity for gene-editing R&D, and potential Bank investment priorities	\$ 120,000.00	\$ 0.00	\$ 120,000.00
Breakout case studies of country-crop specific gene-editing applications	\$ 100,000.00	\$ 0.00	\$ 100,000.00

under different regulatory scenarios			
Pubilc dissemination	\$ 80,000.00	\$ 0.00	\$ 80,000.00

V. Executing Agency and Execution Structure

- 5.1 The TC will be executed by the Bank through the Environment and Rural Development Division (CSD/RND)
- 5.2 Given the regional nature of the technical cooperation, the execution of the TC will be carried out by the Bank through the Environment and Rural Development Division (RND/CBO). The activities to be executed in the proposed TC will be included in a procurement plan and will be contracted in accordance with Bank policies as follows: (a) AM-650 for Individual consultants; (b) GN-2765-1 and Guidelines OP-1155-4 for Consulting Firms for services of an intellectual nature and; (c) GN-2303-20 for logistics and other related services.

VI. Project Risks and Issues

- 6.1 Major risks include: (i) changes in leadership, resource patterns, organizational and/or political priorities, communication failures (internal and external to the organization), resistance to change from invested parties and fatigue in implementation. To mitigate any potential disruption, the technical assistance will be contextually appropriate, modular and flexible, with identification and sustained monitoring of threats in implementation. Engagement with the decision makers will be constant to ensure an efficient approach in the execution of project activities. As the TC will be executed by the Bank, it does not present risks related fiduciary management. Therefore, it will not require financial auditing.

VII. Environmental and Social Classification

- 7.1 The ESG classification for this operation is "undefined".