

TC Document

I. Basic Information for TC

▪ Country/Region:	REGIONAL
▪ TC Name:	Agile Regulation for Innovation in Developing Countries
▪ TC Number:	RG-T4253
▪ Team Leader/Members:	Stevenson, Claudia (IFD/CTI) Team Leader; Acosta, Geovana (IFD/CTI) Alternate Team Leader; Dohnert De Lascrain, Sylvia Eva (IFD/CTI); Gottsch, Marieke (IFD/CTI); Jimenez Mosquera, Javier I. (LEG/SGO); Junho Lee (IFD/CTI); Mayrett Sierra (IFD/CTI); Pombo Rivera, Cristina (SCL/SCL)
▪ Taxonomy:	Research and Dissemination
▪ Operation Supported by the TC:	N/A
▪ Date of TC Abstract authorization:	.
▪ Beneficiary:	Latin American and the Caribbean
▪ Executing Agency and contact name:	Inter-American Development Bank
▪ Donors providing funding:	OC SDP Window 2 - Institutions(W2C)
▪ IDB Funding Requested:	US\$150,000.00
▪ Local counterpart funding, if any:	US\$0
▪ Disbursement period (which includes Execution period):	36 Months
▪ Required start date:	
▪ Types of consultants:	Individuals
▪ Prepared by Unit:	IFD/CTI-Competitiveness, Technology and Innovation Division
▪ Unit of Disbursement Responsibility:	IFD/CTI-Competitiveness, Technology and Innovation Division
▪ TC included in Country Strategy (y/n):	Y
▪ TC included in CPD (y/n):	N
▪ Alignment to the Update to the Institutional Strategy 2010-2020:	Productivity and innovation; Institutional capacity and rule of law; None

II. Objectives and Justification of the TC

- 2.1 The main objective of this Technical Cooperation is to promote dialogue and knowledge of the new trends in regulation that adapt to rapid technological change and innovation. The specific objectives are to: (i) assess the gaps in the region related to the implementation of agile regulation; and (ii) pilot agile regulatory reforms in at least two countries in the region.
- 2.2 **Agile Regulation and Technological Innovations.** Technological innovation has contributed to economic transformation and growth and has the potential to address many of the world's social and environmental challenges, while contributing to economic revival and growth. The new trends in innovation, related to the fourth industrial revolution given its versatility and rapid evolution, require a regulatory environment that adapts to its characteristics, and at the same time maintains the principles of protection of the population and risk mitigation. The regulation of technological innovations requires,¹ on the one hand, providing mechanisms to

¹ World Economic Forum. 2020. Agile Regulation for the Fourth Industrial Revolution: A Toolkit for Regulators.

address humanitarian, environmental and social issues and, on the other, being dynamic, flexible and effective.² Likewise, to the extent that innovation has become a more participatory good through schemes such as *crowd funding*, open innovation, digitalization and access to information and partnerships between the public, private, academic and civil society sectors, innovation regulation must also adapt to this new reality.³

- 2.3 Agile regulation has been defined as a new form of regulation that adapts to the rapid technological changes and acknowledges the importance to have regulation in place that promotes innovation⁴ and that adopts a pace that is congruent with the speed of technological change. The challenges imposed by the Fourth Industrial Revolution, the fast pace of technological change and the complexities involved in disruptive innovation call for a new approach in regulatory practice that involves: (i) openness; (ii) proportionality; and (iii) fairness.⁵ Developed countries are moving forward to adopt agile regulations that foster innovation,⁶ while the countries in the Latin-America and the Caribbean (LAC) region, although they are taking steps toward Industry 4.0, innovation, and new technologies, still lag in the adoption of Agile Regulation.
- 2.4 The greatest advances in the application of Agile Regulation in developed countries are observed in aspects such as identifying a priori the regulatory needs and impacts of technological innovations, spaces for regulatory experimentation, development of data-intensive regulations and introduction of legal and regulatory elements that allow to correct bottlenecks in the development of new ideas, products, or business models.⁷
- 2.5 In that sense, Agile Regulation can be a valuable approach to specifically address the regulation of emerging technologies, such as Automated Decision-making Systems (ADS), that increasingly impact our daily lives. ADS using Artificial Intelligence (AI) is a rapidly evolving technology, and it can be challenging for traditional regulatory frameworks to keep up with its pace of development. In this context, agile regulation, emphasizing flexibility, collaboration, and ongoing monitoring and adjustment, can be a valuable approach to help regulators adapt to the rapidly changing landscape of AI technology.
- 2.6 Using an agile approach to develop and implement ADS regulations, regulators can engage with stakeholders and experts in developing regulations, collect feedback and data, and adjust the regulatory framework as needed. This iterative and collaborative approach can enable regulators to respond quickly to changes in the market or technology and develop regulations that are effective, flexible, and responsive to the concerns of stakeholders.
- 2.7 For example, in the case of Sweden, where a Technological Innovation and Ethics Committee was established by the Swedish government in 2018,⁸ progress has been made in regulating the rules for Artificial Intelligence, in order to strengthen

² OECD. 2022. [Agile Regulation for the Future](#).

³ KDI School of Public Policy and Management. 2021. Regulatory Reform for Fostering an Innovation Ecosystem.

⁴ World Economic Forum. 2018. Agile Governance: Reimagining Policymaking in the Fourth Industrial Revolution.

⁵ World Economic Forum. 2020. Agile Regulation for the Fourth Industrial Revolution: A Toolkit for Regulators.

⁶ OECD. Recommendations of the Council for Agile Regulatory Governance to Harness Innovation

⁷ WEF. 2020.

⁸ Ibid.

competitiveness and at the same time protect health, fundamental rights and promote the positive aspects of AI. It includes considerations of human rights, right to privacy, freedom of expression, non-discrimination, fairness, personal integrity, protection of individuals in the processing of personal data and cybersecurity.⁹

- 2.8 In the case of South Korea, where government policies have prioritized economic growth through innovation in the green and digital sectors, through data-driven services, there is awareness that regulatory barriers¹⁰ have limited the ability to make technological innovations, even though the country has a highly educated workforce, produces a large number of patents and invests heavily in research and development.¹¹ In that sense, starting in 2018, the Korean Government launched a "regulatory sandbox", introduced new legislation to accelerate the development of medical technologies and made changes to the legislation on data handling. However, the changes made have not had the expected impact, requiring long processing times and complex approval procedures. For example, in the "regulatory sandbox", the new legislation on data handling contains inconsistencies and has not generated the necessary trust between the parties. In the area of bioeconomy, the government drew up a plan to triple its market share for medical devices and new medicines. To this end, it carried out the following regulatory reforms: (i) Law on Regenerative Medicine; (ii) Innovative Medical Device Act; (iii) In Vitro Diagnostics Act; and (iv) The Law on Protection of Information and Medical Information. These laws clarify several previous contradictory regulations and speed up approval procedures. However, there is still a need for further reforms and the elimination of positive regulation in other areas of the biomedical sector.¹²
- 2.9 There are examples of initiatives in LAC, such as Costa Rica who developed a roadmap for the establishing of the guiding framework for responsible and ethical use of Artificial Intelligence, aligned with the Digital Agenda was developed, contributing to the policy making and development of an AI strategy. However, the scope of Agile Regulation is broader, and this policy is still incipient.¹³
- 2.10 In general terms, the lack of data and monitoring and evaluation systems, combined with the speed of innovations, means that to date there are no robust evaluations on the impact of the application of these new regulatory methodologies for innovation.
- 2.11 In this regard, the present TC seeks to identify areas in which agile regulation can be successfully applied in the LAC region, such as automated decision-making systems,¹⁴ and thus foster innovation through an adequate regulatory framework. The issues are tackled at the regional level, as many transformative innovations have influence beyond a specific country, applying lessons learned from other jurisdictions. In addition, agile regulation may need to take into account international treaties or international best practices.¹⁵ The Competitiveness, Technology and Innovation

⁹ Ministry of Rural Affairs and Infrastructure. 2021. [Regulation on Artificial Intelligence](#).

¹⁰ Korea uses "positive regulation" meaning it only allows the development of new technologies in areas that are authorized by law.

¹¹ KDI School of Public Policy and Management. 2021. Regulatory Reform for Fostering an Innovation Ecosystem.

¹² Ibid.

¹³ "Support for the guiding framework for the responsible and ethical use of Artificial Intelligence in Costa Rica" (ATN/OC-18579-CR).

¹⁴ This will complement and work hand in hand with other initiatives at the Bank looking for the impact of emerging technologies such as [Fair LAC](#).

¹⁵ OECD. 2021. Recommendations of the Council for Agile Regulatory Governance to Harness Innovation.

Division has approved nine Policy Reform Operations that incorporate measures to improve productivity, innovation and resilient growth.¹⁶ The Policy Matrix of many of them include state of the art reforms in topics such as Public Procurement for Innovation, Building Information Modeling, and Digital Transformation among others, showing that there would be interest in the region to include a next generation of reforms that can be included in the reform dialogue with the countries. The topic of agile regulation has not been included in previous technical assistance or loan programs at the Bank.

- 2.12 The operation is consistent with the Second Update to the Institutional Strategy 2020-2023 (AB-3190-2) and is aligned with the development challenge of productivity and innovation as it promotes innovation through the application of agile regulation. It is also aligned with the objectives of the Strategic Development Program for Institutions (GN-2819-14) as it promotes agile regulatory reforms in the region. The operation is also aligned with the cross-cutting themes of: (i) Institutional Capacity and Rule of Law as it strengthens the institutions in charge of regulation and innovation; (iii) Productivity and Innovation as it supports more productive and innovative economic activities by applying the correct regulation. The operation is aligned with the intervention areas of the Corporate Results Framework 2020-2023 (CRF) (GN-2727-12), namely: (i) support for new or improved environmental legislation and/or governance, including financial mechanisms and incentives targeted at promoting environmental sustainability. It is also aligned with the Priority Area 3: Effective and Transparent Institutions of the Ordinary Capital Strategic Development Program (OC SPD GN-2819-14) was included as this TC will promote more efficient regulation for effective innovation.
- 2.13 This TC will support dialogue in the region regarding the implementation of agile regulation to promote innovation and will focus on concrete cases in a select group of countries in sectors that can be replicated in the region, with a focus on artificial intelligence.

III. Description of components and budget

- 3.1 **Component 1. Identifying Agile Regulations Opportunities in LAC (US\$100,000).** The objective of this component is to strengthen the technical capacity of regulators in LAC to identify and implement agile regulation for innovation. This component will: (i) review recent developments and examples of agile regulation in the global economy; (ii) assess the gaps related to the implementation of agile regulation in the region; and (iii) develop an action plan to identify opportunities of regulatory reform in the LAC region. All of those with a zoom in, when relevant, in specific technologies such as artificial intelligence. For this, the consultant will analyze recent trends in the global economy for regulation for innovation, identify successful examples in key areas of innovation and their key success factors, and analyze the gaps and bottlenecks that hinder the implementation of agile regulation in LAC. Then, the consultant will analyze the status of regulation for innovation in two selected countries, and if applicable in selected sectors and propose and action plan to implement two pilots in the region.

¹⁶ BH-L1050/1052 Boosting Resilient and Inclusive Growth in the Bahamas, CO-L1254 Productive Development and Creative Economy Support Program, PE-L1244/1276 Program to Improve Productivity and Competitiveness, PE-L1283 Reform Program to Support Economic Recovery and Competitiveness II, PN-L1149.67 Economic Diversification and Competitiveness Promotion Program and CH-L1148 Support for Strengthening the Institutional Framework for Science, Technology, Knowledge and Innovation in Chile.

- 3.2 Outputs: (i) Review and identification of global tendencies of agile regulation for innovation; (ii) gap analysis in LAC for agile regulation for innovation with the focus on two selected countries; and (iii) design and develop an action plan for the implementation of two pilot projects for agile regulations.
- 3.3 **Component 2. Design of Pilot Projects (US\$50,000).** This component will support: (i) activities related to designing a roadmap for implementation of two pilot projects for agile regulation in the LAC region. When agreed with a country the pilot could include specific activities for artificial intelligence regulation. The pilots will be selected through a call for proposals¹⁷ and the criteria for selection would be: (a) demonstrated interest in developing a sector in which the absence of agile regulation hinders its development; (b) a sector with rapid changing technology in which there is an interest of the government to protect its citizens from potential negative impacts (such as vaccines, genetically modified organisms' Artificial intelligence. etc.); and (c) potential for implementing a monitoring, evaluation and data collection framework and (d) regional scalability potential. The findings will be discussed and disseminated with stakeholders.
- 3.4 **Outputs:** (i) Draft agile regulation concept notes for two pilots in LAC; and (ii) monitoring and evaluation scheme.
- 3.5 **Indicative Budget.** The total amount of the TC is US\$150,000 to be funded by the Bank through Ordinary Capital (OC) with resources of the W2C-OC of Effective, Efficient and Transparent Institutions fund of the Strategic Development Program (SDP).

¹⁷ To ensure the necessary commitment, selected governments will need to submit a letter of request.

Indicative Budget (US\$)		
Component	Description	Total Funding
Component 1. Identifying Agile Regulations Opportunities in LAC	Strengthening the technical capacity of regulators in LAC to identify and implement agile regulation for innovation.	100,000
1.1 Policy Review	Review and identification of global tendencies in agile regulation and gap analysis for the implementation in LAC	50,000
1.2 Action Plan and design of two pilots	Develop and Action Plan and identify of opportunities of regulatory reform in the LAC region	50,000
Component 2. Design of two pilot projects	Design of two pilot projects to be replicated in the regions	35,000
2.1 Roadmap for implementation of two pilots and draft regulations	Design of Pilot Projects	10,000
2.2 Monitoring and evaluation tool	Monitoring and evaluation tool designed for the pilots	5,000
2.3 Dissemination and diffusion	Dissemination and diffusion activities, workshops, and dialogue	5,000
TOTAL		150,000

- 3.6 **Supervision arrangements.** The designated focal point in the CTI will be the sector specialist assigned by IFC/CTI in Bank Headquarters.

IV. Executing agency and execution structure

- 4.1 **Executing Agency.** The execution will be carried out by the Competitiveness, Technology and Innovation Division at the IDB. CTI will support the identification and supervision of firm and/or individual consultants to ensure the quality and timeliness of the products, according to section 4.5 of the Bank's Technical Cooperation Guidelines (GN-2470-2). As where a regional entity with legal capacity to execute the TC can't be identified – the TC document will make the case that it would be appropriate for the Bank to carry out the contracting of consultants vis a vis the sustainability of the implementation of the project.¹⁸
- 4.2 **Procurement.** The Bank will contract individual consulting services according to the current policies and procedures of the Bank. The contracting of consultants will be carried according to the policies and procedures of human resources (AM-650 complementary workforce), the Policies for Selection and Contracting of consulting firms (GN-2765), the Guidelines OP-1155-4 for Consulting Firms for services of an intellectual nature and the IDB Corporate Procurement Policy (GN-2303-28).

V. Major issues

- 5.1 The main risk for this TC is the need to identify the pilots that could be replicated in the region, and that could provide lessons learned to promote agile regulation in the region. This risk will be mitigated by a highly disseminated call for proposals that will

¹⁸ At the time of the implementation of the pilot projects, non-objection letters from the designated institutional focal points will be required for the selected countries.

allow the participation of all the countries and will highlight the existing demand in the region. In addition, the need to include key stakeholders from public institutions, private sector, NGOs and academia in the identification and implementation of agile regulations will promote the sustainability of the proposed policy reforms. This risk will be mitigated by incorporating best practices in agile regulation such as collaborative approaches to policymaking in the design of the agile policy pilots.

VI. Exceptions to Bank policy

- 6.1 This subheading should identify and address any exceptions to Bank policy.

VII. Environmental and Social Strategy

- 7.1 This TC will not finance feasibility or pre-feasibility studies of investment projects nor associated environmental and social studies; therefore, it does not have applicable requirements from the Bank's Environmental and Social Policy Framework (ESPF).

Required Annexes:

[Results Matrix - RG-T4253](#)

[Terms of Reference - RG-T4253](#)

[Procurement Plan - RG-T4253](#)