



Six Case Studies in Latin America and the Caribbean: Access to Genetic Resources and Benefit Sharing



IUCN's Regional Office for South America



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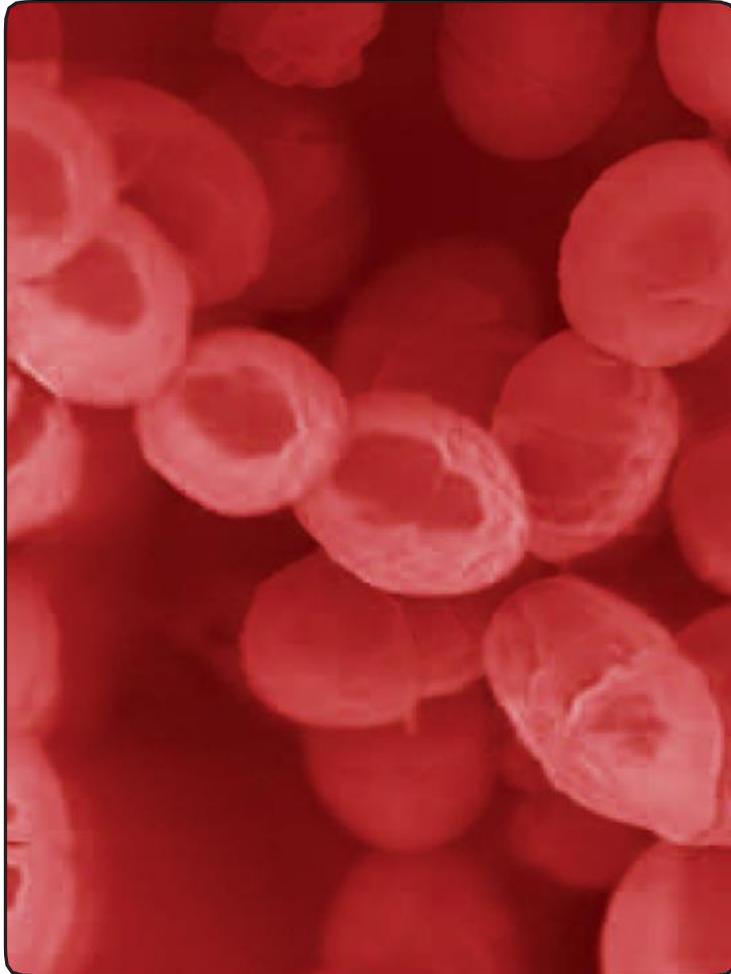
**Strengthening the Implementation of
Regimes of Access to Genetic Resources and
Benefit Sharing in Latin America and the Caribbean**

Montserrat Ríos and Arturo Mora

Editors

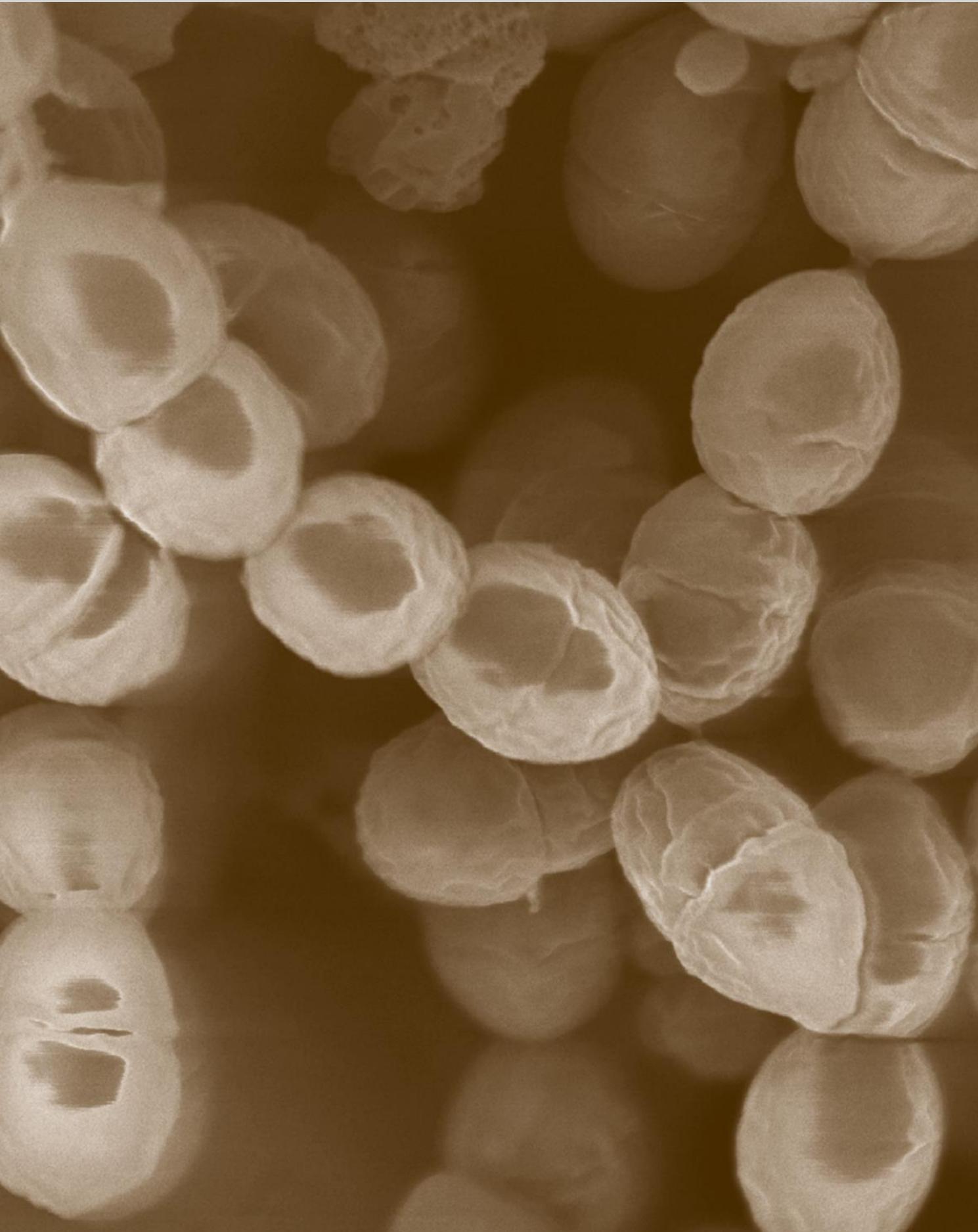
Regional GEF Project “Strengthening the Implementation of Regimes of Access to Genetic Resources and Benefit Sharing in Latin America and the Caribbean” executed by the Regional Office for South of the International Union for Conservation of Nature (IUCN South America) and implemented by the Regional Office for Latin America and the Caribbean of the United Nations Environment Programme (UNEP-ROLAC).

Case Study in Colombia



© *Lactococcus lactis*, Joseph Heintz and Kenneth Todar - University of Wisconsin

Gabriel Ricardo Nemogá-Soto and
Dalí Aleixandra Rojas
Díaz



Research on a microorganism of the genus *Lactococcus* sp., Institute of Biotechnology, National University of Colombia

1. Introduction

Ever since the Convention on Biological Diversity (CBD) entered into force in 1993, the paradigm of open access to biodiversity under the concept of common heritage of mankind has changed with the application of a proprietary approach that redefines the right of countries over genetic diversity. Thus, the trend towards the establishment of intellectual property rights through patents and plant breeders' rights –beginning in the 1920s in the United States and in the 1950s in Europe– is assumed.

In 1992, the sovereignty of countries over their own biodiversity is recognized, establishing the commitment to facilitate the access to genetic resources (Art. 15, CBD). And so it is that in 1996, the states of the Andean Community of Nations set up a Common Regime through Decision 391, creating national regulations geared towards the access and use of genetic resources and traditional knowledge associated to biodiversity by means of obtaining the prior informed consent and mutually agreed terms.

Given the fact that the strengthening of scientific and technological capacities in the Andean Community is one of the main objectives of the Regime, it was decided to conduct a case study in Colombia, not only because the country is a part of this regional community and is bound by all legal implications of Decision 391, but also because it is a megadiverse country.

The selected project describes the state of the art of biotechnology research, with the biological resources represented by a microorganism of the genus *Lactococcus* sp. and its levansucrase enzyme by-product which could have a real or potential use.

The entities in charge of the implementation of this initiative are the National University of Colombia (UNC) through the Institute of Biotechnology, the Research Vice Rectorate and the National Juridical Office, as well as government institutions, namely: the Regional Autonomous Corporation of Cundinamarca (CAR), the Ministry of Environment and Sustainable Development (MADS), and the National Natural Parks of Colombia (PNN).

The analysis of this case study, which still ongoing, offers important lessons for countries seeking to ensure a fair distribution of the benefits derived from their biodiversity as well as their genetic resources. Thus, it is crucial and decisive to suggest that in order to fulfill this premise, the process of strengthening endogenous capacities in science and technology must be improved. It is by accomplishing this that the legislation objectives concerning the access to biodiversity will be achieved.

2. Contractual Agreements

The Obligations and commitments for those implementing the biotechnology project have been detailed in accordance to the provisions of Contract 49, signed in 2012, and pertaining to the access to a by-product for purposes of industrial application and commercial use. Government institutions may follow-up on the project's activities on the basis of the data presented and applying the parameters contained in Decision 391.

2.1 Obligations and permits for scientific research

According to Resolution CAR 383, of August 13, 2001, the obligations derived from the permit consist on submitting the following:

- i. Partial or final reports in accordance with the established schedule.
- ii. Ratio of samples collected.
- iii. Copy of the deposit confirmation.
- iv. Report that describes the method of disposal of unused samples.
- v. Registration of biological collections in the Alexander von Humboldt Institute.
- vi. Copy of the publications.

2.2 Obligations of the access contract for a by-product with industrial application purposes

According to the parties participating research, it is agreed that Contract 49, pertaining to the obligations of the access contract for a by-product with industrial application purposes and commercial use of a levansucrase enzyme complex that has been biochemically isolated and identified from the native microorganism *Lactococcus lactis* and in charge of the synthesis of a biopolymer derived from sucrose. The contract establishes a term of 10 years and describes the obligations of the parties:

Obligations of the National University of Colombia:

- i. Mention Access Contract 49 and name of the genetic resource in question in publications derived from the research.
- ii. Submit to the Ministry of Environment and Sustainable Development as well as to other stakeholders, those results of research which are not confidential.
- iii. Provide the Ministry of Environment and Sustainable Development with reports on the industrial and commercial application of the by-product, presenting one report every year as well as one at the end of the contract. The reports must comply with the guidelines established in Decision 391.
- iv. Comply with the fair benefit-sharing agreement pertaining both, monetary and non-monetary benefits.
- v. Store the microorganism in a deposit or strain bio bank.
- vi. Inform the Ministry of Environment and Sustainable Development as well as the National Support Institution (INA) on the progress of the contract.

- vii. Forward the research and publications derived from the activities of the Project.
- viii. Disseminate non-confidential information to the database of the Institute of Biotechnology at UNC. Obligations of INA correspond to the Technological University of Pereira:
 - i. Accompany and participate with the UNC in access activities.
 - ii. Collaborate with the Ministry in monitoring and control activities.

Obligations of the Ministry of Environment and Sustainable

Development:

- i. Ensure the compliance with contract obligations.
- ii. Evaluate reports and issue concepts.

3. Project and research activities description

3.1 Collection Activity

The environmental authority granting permission to conduct the research study is the CAR, in accordance with Resolution 383 of August 13, 2001. The objective is to isolate and identify a microorganism of the genus *Lactococcus* and check its enzymatic activity to generate the production of a natural-origin polymer. Resolution 383 states that:

- i. The collection of soil samples is conducted in a private estate located in the municipality of La Calera, Cundinamarca.
- ii. The samples are analyzed at the Institute of Biotechnology of the UNC.

3.2 Access to genetic resources

Upon revision of Patent No. 2333599 registered at the Spanish Patent and Trademark Office (worldwide. espacenet.com), the following information was found in relation to the microorganism:

- i. The project identified a method for the production of a sucrose polymer (levan) through a strain of the species *Lactococcus lactis*.
- ii. The biopolymer can be used in the pharmaceutical industry as a plasticizer, thickener, stabilizer, dispersant, film-forming, disintegrant, blood plasma substitute, lubricating agent and prebiotic.
- iii. The biopolymer can be used in the food industry as a thickener, plasticizer; stabilizer, dispersant, fiber and a substitute for fat, oil or carbohydrates which are ether or ester-based.
- iv. The biopolymer can be used in: products obtained by extrusion for forming films which are suitable for producing flexible and biodegradable packaging which is ether or ester-based; disposable biodegradable products made by injection or molding which are ether or ester-

based; and in the production of flocculent agents for water treatment.

4. Detail of benefits included in the agreements

Upon revision of Contract de Access Contract 49 of 2012 for a By-product with Industrial Application Purposes and Commercial Use, signed by the Ministry of Environment and Sustainable Development and the National University of Colombia, hereon referred to as Contract 49, and through a personal communication with José Manuel Martínez (2012), officer of the Research Vice Rectorate, the following benefits were identified:

4.1 Non-monetary benefits

- i. Facilitate the access to microorganisms of the genus *Lactococcus* kept in the bio bank.
- ii. Conduct two workshops, one in the first year of Contract 49 and another in the third year, directed to the environmental authorities, with the objective of demonstrating the importance of biotechnology and its relationship with sustainable use of the genetic resources of the country.

4.2 Monetary benefits associated to industrial property

In the case the UNC obtains a patent in any country, the product and/or procedure obtained or developed from the access to the by-product which is the object of Contract 49 and for which a license were issued for third-party use, shall pay the Ministry of Environment and Sustainable Development an annual 10% of the total revenues perceived on account of the license.

Once the contract is completed, the UNC will not use the by-product for any purpose or claim intellectual property rights over them.

4.3 Monetary benefits associated with the commercial exploitation

In relation to the commercial or industrial use of the products and/or processes developed or derived from the access to the by-product which is the object of this contract and which are not protected by patents, the UNC shall pay to the Ministry of Environment and Sustainable Development an annual fee of 10% of the total amount of royalties received.

4.4 Benefits generated and shared to date

The information regarding the benefits generated and distributed to this date was collected in an interview with Gustavo Buitrago, co-inventor of the patent and professor at the Institute of Biotechnology of the National University of Colombia (Buitrago com. pers. 2012 y 2013).

Buitrago mentions the absence of benefit sharing up to this point, because no license has been granted for the commercial use of the research results. However, the Institute of Biotechnology signed two agreements with the company PROCAPS a few years back.

The first of these agreements was signed in 2002 and it consisted on determining if it was possible to make biopolymer capsules. Hence, the company funded researchers with 20 million Colombian pesos (US\$10,500 at an exchange rate of 1904.76 Colombian pesos per dollar) and the Institute of Biotechnology contributed with its prior knowledge and the biopolymer.

Since there were positive results from the first agreement, the signing of a second agreement was decided in 2003 with the goal of building a pilot plant for biopolymer production. This time PROCAPS funded the construction of the pilot plant with 1,300 million Colombian pesos (US\$ 682,501 at an exchange rate of 1904.76 Colombia pesos per dollar), and the size of the industrial plant was also determined. The capsule production was not viable from an economic standpoint, and this was the reason why the pilot plant is partially dismantled at the company's facilities. If a sound business plan had been achieved, PROCAPS would have had preference in the licensing of the patent.

5. Scope and status of project activities

5.1 Research status

Currently, the research status shows that markets for polymers are still being explored, and the research on identifying new applications is advancing (Buitrago com. pers. 2012).

5.2 Traceability and monitoring mechanisms

In accordance with Contract 49 it is stipulated that:

- i. Publications are a monitoring tool.
- ii. Four reports on the progress of activities must be submitted, one each year. It must be clear that: "Such reports shall be elaborated in accordance with the authorized access activities and the obligations stipulated in this contract" (Clause 11).

5.3 Impact on local socio-economic and/or institutional conditions

Information regarding the impact on local socio-economic conditions and/or institutional was collected based on interviews with Gustavo Buitrago, co-inventor of the patent and professor at the Institute of Biotechnology of the National University of Colombia, and Carlos Ospina, specialist of the Ministry of Environment (Buitrago com. pers. 2012 y 2013; Ospina com. pers. 2013).

- i. For the UNC: financial support in the construction of a pilot plant; issuing of publications; implementation of cooperation agreements with other educational or research institutions; funding for participation in or organization of academic events; strengthening of the infrastructure for the collection of microorganisms; donation of lab equipment for the Institute of Biotechnology, and creation of job opportunities for graduates of their academic programs.
- ii. For the Ministry of Environment and Sustainable Development: institutional reorganization and negotiating capacities in access contracts for commercial purposes.

5.4 Information regarding the request for Intellectual Property Rights and its status

The patent has been granted in Spain, France and the UK. The request has been withdrawn in Japan (2006546384) and the paperwork is still going on in the United States (US2007141667 A1) (Buitrago com. pers. 2012).

5.5 Description of conflicts or agreements reached

According to interviews with Gustavo Buitrago and Carlos Ospina data was collected regarding the conflicts which came up and the agreements reached during the duration of the project (Table1), thus finding solutions for situations that contributed to the process to move on with greater efficiency (Buitrago com. pers. 2012; Ospina com. pers. 2013).

Table 1. Conflicts and agreements during the project for biotechnology related to the species *Lactococcus lactis* and its levansucrase enzyme by-product.

Conflict	Agreement
Lack of systematization of the verbal agreements Between the National University of Colombia and the Ministry of Environment and Sustainable Development.	Minutes for the meetings have been elaborated for the last two years.
Research stagnation due to the precautionary measure imposed by the Ministry of Environment and Sustainable Development.	Signing of Contract No. 49 for commercial research purposes includes research on possible uses of biopolymer.
Disinformation between the Institute of Biotechnology and the Vice Rectorate of Research of the National University of Colombia regarding the request for access to genetic resources.	The Vice Rectorate of Research of the National University of Colombia participated in the negotiation process, legally supporting the Institute of Biotechnology and taking on the responsibility for the procedure of access to genetic resources.

6. Lessons Learned

Among the lessons learned, particularly due to the legal complexities and difficulties encountered during the project, the following can be highlighted:

- i. Experience and initial setting of parameters for contracts for access to genetic resources with commercial purposes.
- ii. Specialized management of the National University of Colombia in relation to PEFIC contracts for access to genetic resources.
- iii. Recognition of the complexity and high degree of specialization required for the procedures to obtain access to genetic resources, where the creation of a group of access to genetic resources in the Ministry of Environment and Sustainable Development is a strategic action.
- iv. Need for explanatory guides for the users of the regime of access to genetic resources.

- v. It must be pointed out that at the moment there are still no perspectives regarding access and benefit sharing, or regarding the impact on the socio-economic conditions of the local population.

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