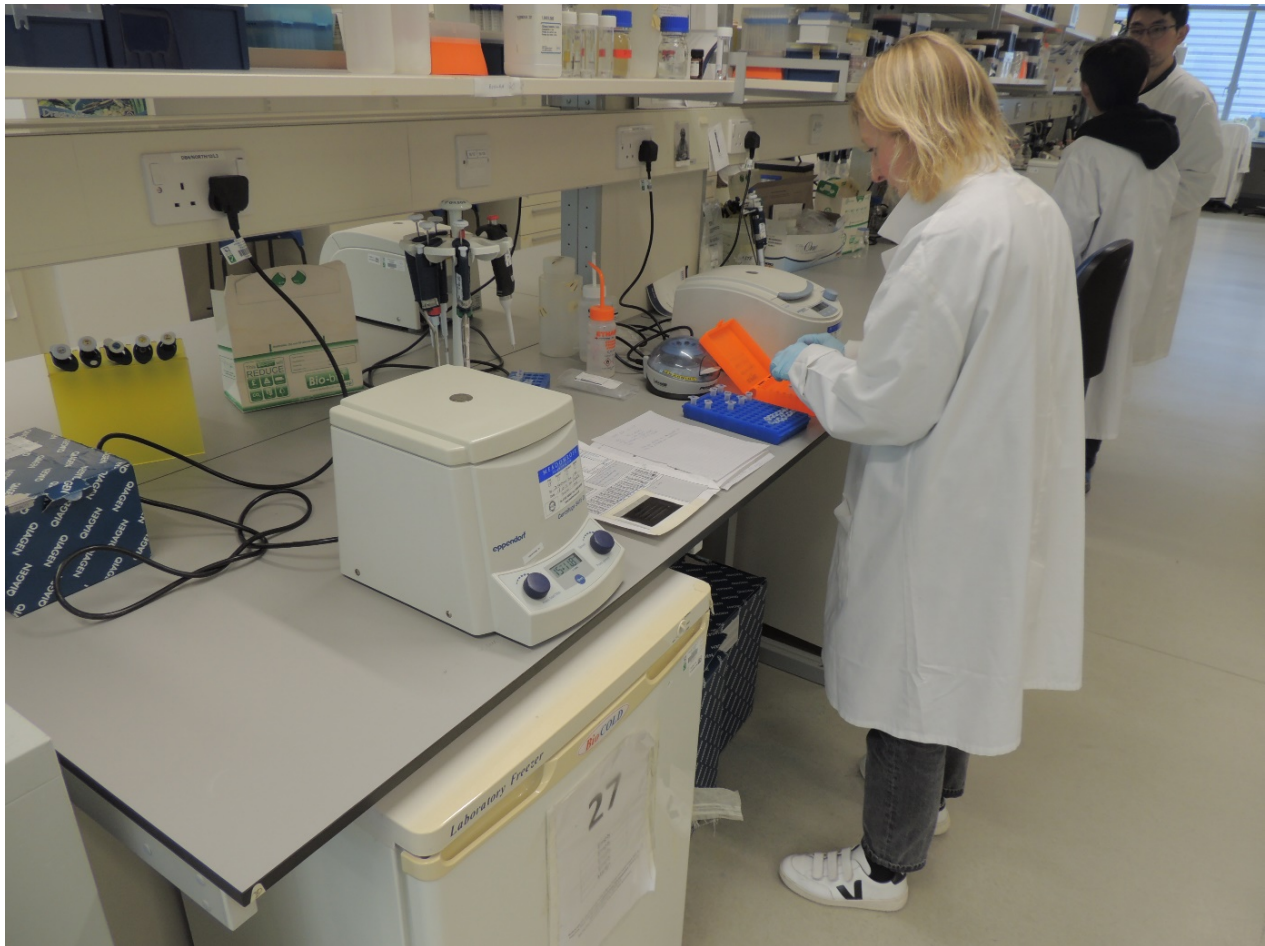


Evanson Chege Kamau (Ed.)

# Implementation of the Nagoya Protocol

## Fulfilling new obligations among emerging issues



# **Implementation of the Nagoya Protocol**

## **Fulfilling new obligations among emerging issues**

**Edited by**  
**Evanson Chege Kamau**



**Cover picture:** Laboratory at the Natural History Museum, London (Chris Lyal)

**Editor's address:**

Dr. Evanson Chege Kamau

Universität Bremen  
Universitätsallee, GW 1  
28359 Bremen  
E-Mail: echege@uni-bremen.de

**Scientific supervision:**

Thomas Greiber

BfN, Division I 1.3 "Competent National Authority for the Nagoya Protocol"

This study was funded by the German Ministry for the Environment, Nature Conservation and Nuclear Safety as Research & Development project (FKZ: 3517 81 010E).

This publication is included in the literature database "DNL-online" ([www.dnl-online.de](http://www.dnl-online.de))

BfN-Skripten are not available in book trade. A pdf version can be downloaded from the internet at: <http://www.bfn.de/skripten.html>.

Publisher: Bundesamt für Naturschutz (BfN)  
Federal Agency for Nature Conservation  
Konstantinstraße 110  
53179 Bonn, Germany  
URL: <http://www.bfn.de>

The publisher takes no guarantee for correctness, details and completeness of statements and views in this report as well as no guarantee for respecting private rights of third parties. Views expressed in this publication are those of the authors and do not necessarily represent those of the publisher.



This series is distributed under the terms of the Creative Commons License Attribution – No Derivatives 4.0 International (CC BY - ND 4.0) (<https://creativecommons.org/licenses/by-nd/4.0/deed.en>).

Printed by the printing office of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety

Printed on 100% recycled paper.

ISBN 978-3-89624-325-6

DOI 10.19217/skr564

Bonn, Germany 2019

## Table of Contents

<b>Contributors</b> .....	<b>iv</b>
<b>Acknowledgements</b> .....	<b>vi</b>
<b>List of Figures</b> .....	<b>vii</b>
<b>List of Abbreviations / Acronyms</b> .....	<b>viii</b>
<b>PART I: INTRODUCTION</b> .....	<b>1</b>
Chapter 1 Implementing the Nagoya Protocol and new arising issues: Introduction, observations and conclusions	
Evanson Chege Kamau .....	<b>3</b>
<b>PART II: ABS MEASURES AND IMPLEMENTATION OF NAGOYA PROTOCOL REQUIREMENTS: CASE STUDIES</b> .....	<b>13</b>
Chapter 2 Viet Nam: New ABS legislation and practice, compliance with the Nagoya Protocol	
Tran Thi Huong Trang, Nguyen Ba Tu & Nguyen Dang Thu Cuc .....	<b>15</b>
Chapter 3 Korean ABS law	
Jae-Hyup Lee & Ah Young Cho .....	<b>23</b>
Chapter 4 The Malaysian ABS law – A big step forward	
Evanson Chege Kamau .....	<b>27</b>
Chapter 5 Implementing ABS in Australia. Failing at the last hurdle?	
Geoff Burton.....	<b>35</b>
Chapter 6 The South African ABS regime: Between old and new	
Evanson Chege Kamau .....	<b>41</b>
Chapter 7 Towards a Nagoya Protocol compliant ABS regulatory framework in Cameroon	
Marcelin Tonye Mahop.....	<b>49</b>
Chapter 8 The Ethiopian ABS regime	
Ashenafi Ayenew Hailu .....	<b>55</b>
Chapter 9 The Kenyan ABS regulations: A static law	
Evanson Chege Kamau .....	<b>59</b>
Chapter 10 Brazil: New ABS legislation and practice	
Lilian Massini Mozini .....	<b>65</b>
Chapter 11 ABS regime in Argentina	

Luciana Carla Silvestri.....	73
Chapter 12 Costa Rican ABS legislation and practice	
Jorge Cabrera Medaglia.....	77
Chapter 13 ABS in Ecuador and Peru: Between the Andean sub-regional regime and the Nagoya Protocol	
Maria Victoria Cabrera Ormaza.....	83
Chapter 14 The post Nagoya Protocol ABS regulatory framework of France	
Marcelin Tonye Mahop.....	91
Chapter 15 ABS regime in Spain	
Luciana Carla Silvestri.....	99
<b>PART III: CRITICAL THEMES AND IMPLEMENTATION.....</b>	<b>103</b>
Chapter 16 ABS regulation in the European Union	
Gerd Winter.....	105
Chapter 17 Disentangling Due Diligence – Making sense of the EU Regulation 511/2014 transposing the Nagoya Protocol	
Christine Godt & Markus Burchardi.....	111
Chapter 18 Implementation of Due Diligence obligations in Germany	
Thomas Greiber.....	115
Chapter 19 Current situation on Digital Sequence Information (DSI)	
Christopher H C Lyal.....	119
Chapter 20 The persistence of ABS contractual obligations in the context of agricultural breeding	
Marie Schloen.....	125
Chapter 21 Post Nagoya Protocol experiences of academic biodiversity-related research in Ecuador	
Erwin Beck.....	131
Chapter 22 Rights over genetic resources and ways of monitoring the value chain. A case study from the Royal Botanic Gardens, Kew	
China Williams.....	137

## Contributors

- Ah Young Cho, PhD Candidate, Seoul National University School of Law, South Korea. hasiromi5@snu.ac.kr.
- Ashenafi Ayenew Hailu, Director, Genetic Resource Access and Benefit Sharing Directorate, Ethiopian Biodiversity Institute, Addis Ababa, Ethiopia. aye-newashenafi2007@gmail.com.
- China Williams, Senior Science Officer (Policy), Royal Botanic Gardens, Kew, UK. c.williams@kew.org.
- Christine Godt, Prof. Dr., Chair for European and International Economic Law, Civil Law, Carl von Ossietzky University of Oldenburg; Director Hanse Law School. Germany. christine.godt@uni-oldenburg.de.
- Christopher H C Lyal, Dr., Department of Life Sciences, Natural History Museum, Cromwell Road, London SW7 5BD, UK. c.lyal@nhm.ac.uk.
- Erwin Beck, Prof. Dr., Department of Plant Physiology and Bayreuth Centre of Ecology and Environmental Research, University of Bayreuth, Bayreuth, Germany. erwin.beck@uni-bayreuth.de.
- Evanson Chege Kamau, Dr., Senior Research Fellow, Research Centre for European Environmental Law, University of Bremen, Germany. echege@uni-bremen.de.
- Geoff Burton, Principal Consultant, Genetic Resources Management, Jean Shannon & Associates, Australia. geoff@jeanshannon.com.
- Gerd Winter, Prof. Dr., Research Professor of public law and sociology of law, University of Bremen, Germany. gwinter@uni-bremen.de.
- Jae-Hyup Lee, Prof., Seoul National University School of Law, South Korea. jhyup@snu.ac.kr.
- Jorge Cabrera Medaglia, Prof., Professor of Environmental Law, University of Costa; Legal adviser, National Biodiversity Institute, Costa Rica. jorgemedaglia@hotmail.com.
- Lilian Massini Mozini, Legal consultant in environmental law specialising in development of strategies for biodiversity access, innovation and products development for companies and research institutions, Brazil. Imozini@ambiente-global.com.
- Luciana Carla Silvestri, Dr., Institute of Human, Social and Environmental Sciences (INCIHUSA) – National Council of Scientific and Technical Research (CONICET), Av. Ruiz Leal s/n, Ciudad de Mendoza, Argentina. lsilvestri@mendoza-conicet.gob.ar.
- Marcelin Tonye Mahop, Dr., Research Fellow, Sustainability Research Institute (SRI), School of Earth and Environment (SEE), Faculty of Environment, University of Leeds, UK. tonye2169@gmail.com or m.tonyemahop@leeds.ac.uk.
- Maria Victoria Cabrera Ormaza, Dr., Legal Officer at the International Labour Office. Former associate professor and researcher at the Universidad Espiritu Santo-Ecuador. marvic.co@gmail.com.
- Marie Schloen, PhD Candidate, University of Bremen, Germany. mschloen@yahoo.com.
- Markus Burchardi, PhD candidate and research assistant at the Chair for European and International Economic Law. markus.burchardi@uni-oldenburg.de.

Nguyen Ba Tu, Ministry of Natural Resources and Environment, Hanoi, Viet Nam.  
tunguyen.bca@gmail.com.

Nguyen Dang Thu Cuc, Ministry of Natural Resources and Environment, Hanoi, Viet Nam.  
nguyendt.cuc@gmail.com.

Thomas Greiber, Head of Division I 1.3, Federal Agency for Nature Conservation (BfN) – Competent National Authority for the Nagoya Protocol, Bonn, Germany. thomas.greiber@bfn.de.

Tran Thi Huong Trang, Dr., Independent legal consultant in biodiversity, natural resources and environmental law, Viet Nam. tranglpsd@gmail.com.

## Chapter 13

# ABS in Ecuador and Peru: Between the Andean sub-regional regime and the Nagoya Protocol

Maria Victoria Cabrera Ormaza<sup>1</sup>

## 1 Introduction

Ecuador and Peru are parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol). Both countries are, at the same time, bound by a sub-regional access and benefit-sharing (ABS) regime established within the Community of Andean Nation (CAN) in 1996. The Andean ABS regime is contained in the Decision 391 “Common Regime on Access to Genetic Resources”, which was adopted by the Commission of the Cartagena Agreement<sup>2</sup> in 1996. This Decision is based on the understanding that countries are sovereign in the use of genetic resources (GRs), in line with the Convention on Biological Diversity.<sup>3</sup> It prescribes requirements and conditions for accessing GRs, which are aimed at strengthening the authority of the provider country vis-a-vis the user.

In practice, the Andean regime has proven complex and difficult to implement.<sup>4</sup> The ratification of the protocol by Ecuador and Peru has posted challenges to these countries, which are under the obligation to ensure “appropriate access to genetic resources” by, among others, providing for clear, transparent and non-arbitrary ABS rules and procedures.<sup>5</sup> While steps are being taken to achieve this goal, there appear to be critical areas in which the national legislations of these countries continue to reflect the over-regulatory approach embedded in the Andean decision. This contribution explains the current ABS legal framework in Ecuador and Peru, outlining some of these critical areas, in three steps. First, it briefly explains the rationale and the main elements of Decision 391. Second, it describes the existing national ABS legislation of Peru and Ecuador, focusing mainly on the scope of coverage, the definitions of ‘genetic resources’, ‘access’, and ‘utilisation of GRs’; the difference in the treatment given to commercial and non-commercial research, requirements concerning traditional knowledge and transfer of material, and rules concerning benefit-sharing. This article concludes with an assessment, pointing out the challenges ahead.

## 2 The Andean ABS regime: Decision 391

The adoption of Decision 391, as a sub-regional instrument on ABS directly applicable in Andean countries,<sup>6</sup> was supposed to help Andean countries to strengthen their political power in international negotiations concerning biodiversity as well as to prevent biopiracy.<sup>7</sup>

---

<sup>1</sup> The author expresses her sincere thanks to the Universidad Espiritu Santo-Ecuador which provided support for the conduction of this research at its early stage and to Deyanira Camacho, Maria Consuelo Velasco, and Lily Rodriguez for their guidance and support in this research. The views expressed in this chapter are the author's own and do not reflect the position of the International Labour Organization or its member states.

<sup>2</sup> At the time of this writing, the countries bound by this regime are Ecuador, Peru, Bolivia and Colombia. Only Colombia has not yet ratified the Nagoya Protocol.

<sup>3</sup> Decision 391, Preamble.

<sup>4</sup> Ruiz Muller M. (2003), 3.

<sup>5</sup> Nagoya Protocol, Art. 6.

<sup>6</sup> Treaty establishing the Tribunal of Justice under the Cartagena Agreement, Art. 2.

<sup>7</sup> Caillaux, J. et al. (1999), 7.



This second aspect was particularly critical at the time of the negotiations of an ABS regime in the CAN, given that the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) came into effect in 1995, reinforcing the protection of intellectual property rights over scientific inventions.<sup>8</sup>

## **2.1 Underlying principles and scope**

The Preamble of Decision 391 recognises the sovereign right of the state to decide over the use of GRs, the economic and strategic value of GRs, the contribution of indigenous and local communities to biological diversity through their traditional knowledge (referred to as 'intangible component') as well as the intrinsic relation between biodiversity and such knowledge. Overall, Decision 391's approach is strictly regulatory and has as its main objective the establishment of conditions for a just and equitable participation of the state in the benefits derived from the access to GRs (Article 2). As regards its scope, it applies to GRs in respect of which Andean countries are the countries of origin, their derivatives and intangible components; as well as to migratory species which, for natural reasons, are found in the territories of the member countries (Article 3). Human GRs as well as GRs that are used for subsistence of indigenous and local communities are excluded from the scope of the Decision (Article 4).

## **2.2 Key definitions and basic procedure**

Article 1 of Decision 391 provides the definitions of 'access', 'genetic resources' 'derivatives' and 'intangible component'. Access implies both "obtaining and use of GRs", conserved in situ and ex situ, of their derivatives and, if applicable, of their intangible components, for a non-exhaustive list of purposes, including, research, biological prospecting, conservation, industrial application and commercial use. Genetic resources are defined as "all biological material that contains genetic information of value of real or potential use". Derivatives comprise "a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings"; whereas the intangible component is defined as "all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resources, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes".

An important contribution of the Andean Decision is that it provides for general ABS rules and an access procedure, which is to be adapted to national circumstances. This procedure involves a request for access which, if approved, leads to the conclusion of an access agreement. This is followed by the issuance of a resolution granting access that must be registered in a public registry. An indispensable condition for obtaining access is the participation of a local university or research institution in the access activities. This institution is referred to as the 'national support institution' (Article 26). It should be noted that Decision 391 provides for the possibility that the competent national authority in charge of granting access, conclude 'framework access agreements' with individual researchers, research centres or universities (Article 36). In practice, this has been understood and applied at the national level as an abbreviated procedure for obtaining access to GRs for non-commercial purposes.

---

<sup>8</sup> Gomez Lee, M. (2012), 46.

Based on Decision 391, Ecuador and Peru have designed their own national regulations, defining thereby the roles of the competent national authorities. In doing so, they have further developed important aspects concerning ABS, as described below.

### **3 Peru**

Peru ratified the Nagoya Protocol in October 2014. However, the Peruvian first ABS domestic regulation dates back to 2009, and is primarily based on the Andean Decision 391's regulatory approach. This regulation was drafted by the Ministry of the Environment and approved by the Supreme Decree No. 003-2009. Its main objective, as reflected in its Article 1, is to establish conditions for a fair and equitable sharing of benefits arising out of the access to GRs, in order to implement the Andean Decision. The regulation has the same scope of application as Decision 391, but adds into the list of excluded areas the species covered by the International Treaty on Plant Genetic Resources for Food and Agriculture; use of GRs for plant breeding within the national territory and activities that concern the use of non-wood natural resources to produce nutraceutical products and functional food (Article 5).

The 2009 regulation appoints the Ministry of the Environment as the leading agency on ABS matters (Article 13), accompanied by three executing entities in charge of authorising access depending on the type of GRs: The Ministry of Agriculture with respect to wild species; the National Institute of Agrarian Innovation for domesticated species and the Vice-Ministry of Fisheries with respect to marine species (Articles 14 and 15). The Ministry of the Environment is tasked with designing and adopting the national ABS policy and law, coordinating the activities of the three executing agencies, and monitoring compliance with the national regulation. The executing agencies, for their part, must examine and approve access requests, negotiate and conclude ABS agreement in their respective spheres of competence subject to the favourable opinion of the Ministry of the Environment, adopt ABS sectorial policies, and monitor compliance with access agreements.

Procedurally, the 2009 regulation does not modify the ABS procedure contained in Decision 391. However, it specifies the requirements for the access agreement, such as the recognition of the origin of the GRs, the involvement of locals in the research activities and the transfer of knowledge and technology. Aside from this, access agreements shall contain clauses providing for the user's obligations to report on research outcomes to the authority that granted the permission for access as to give an economic compensation to the country of origin for the benefits arising out of access and utilisation of GRs. In addition, the regulation indicates the requirements for the agreements that need to be concluded by the user with ex situ conservation centres, the holder of the intangible component and the national support institution. With respect to the latter, the Peruvian regulation appears to over emphasise the supervisory role of the national support institution (Articles 18 and 19), arguably giving less attention to its function as research partner as was originally envisaged by Decision 391.<sup>9</sup> The conditions for the conclusion of a framework agreement for non-commercial research are spelled out in the 2009 regulation (Articles 24 to 26). These include the involvement of local researchers in activities of collection, research and the production of scientific data, and reporting obligations to the national authorities. However, no specific procedure addressing change of intent from commercial to non-commercial research can be found. Finally, the 2009 regulation stipulates that transfer of material to ex situ conservation centres is subject to the conclusion of an Agreement of Transfer of Material, which is to

---

<sup>9</sup> Silvestri L. (2016), 76.

be jointly approved by the Ministry of the Environment and the entity which authorises access (Articles 29 to 33).

Access and use of the collective knowledge of indigenous communities associated to GRs is regulated separately by the Act No. 27.811 of 2002. This Act defines collective knowledge as “the accumulated and transgenerational knowledge developed by indigenous peoples and communities regarding the properties, use and characteristics of biological diversity” and requires the prior and informed consent of the concerned community with regards to its access and utilisation (Articles 1 and 6). To obtain the community’s consent, the user shall provide the community with the relevant information on the purposes, risks and consequences of the access activities, including the potential uses of their collective knowledge. Notably, the Act states that when the collective knowledge is used for commercial or industrial application, the user shall negotiate and conclude with the concerned indigenous community a licence agreement stipulating the conditions of the use and the distribution of benefits (Article 7). Benefits for the community shall not be less than 10 per cent of the gross sales resulting from the utilisation of GRs, before tax deductions (Article 8).

A new ABS regulation has been drafted and submitted for nation-wide consultation in July 2019. The proposed legislation is contained in the Resolution No. 205-2019 issued by the Ministry of the Environment. Though it does not substantially modify the existing ABS procedure, it introduces new definitions and modifies some of the existing ones. Interestingly, the proposed legislation seeks to implement both Decision 391 and the Nagoya Protocol (Preamble), which appears to imply an understanding of the two instruments as mutually supportive. It keeps the definition of access as the process of “obtaining and utilizing GRs”, but it ambiguously defines ‘obtaining’ as the process of “extracting the genetic material and/or their derivatives from biological resources or any other source” (Article 3). This leaves the door open to subject the ‘genetic information’, understood as the “nucleotides sequence obtained from GRs, including sequences digitally stored” (Article 3) to the Peruvian ABS regulation. In doing so, the proposed regulation goes beyond the scope of Decision 391, which does not cover genetic information from digital sources.

Following the requirements of the Nagoya Protocol the proposed regulation incorporates a definition of ‘Mutually Agreed Terms’ (MAT) as “the agreement containing the conditions of use and the rules for benefit-sharing”, and of ‘Prior and Informed Consent’ as “the process through which the Peruvian States grants its consent to access through the competent national authorities, in line with the Convention on Biological Diversity, the Nagoya Protocol and the Bonn Directives”. While a distinction between commercial and non-commercial access is kept, no special procedure has been included to address situations of change of intent.

#### **4 Ecuador**

Ecuador ratified the Nagoya Protocol in September 2017. At the time of this ratification, Ecuador had established substantive and procedural ABS rules in different legal instruments including the 2008 National Constitution, legislative and administrative measures, besides the rules contained in Decision 391. Article 400 of the Ecuadorian Constitution declares as part of the national heritage “the biodiversity and its components, in particular ... the genetic heritage”, which means that access to GRs constitutes a matter of public interest. Notably, the use of GRs is subject to a benefit-sharing rule related to the exploitation of natural resources which is contained in Article 408 of the Constitution. According to this rule, the state shall benefit in an amount which should not be less than the amount of benefits obtained by the person or entity that exploits the natural resources of the state. In prac-

tice, the existence of this rule may create disincentives to users as they may have very limited capacity to bring into the negotiation table other terms of distribution of benefits that take into consideration their concerns and interests.<sup>10</sup>

In October 2011, Ecuador adopted its first ABS regulation with a view to implement Decision 391. This regulation is contained in the Executive Decree No. 905. It restates the definitions of access and of genetic resources contained in the Andean Decision, but incorporates the definition of the term 'benefits' as "both monetary and non-monetary benefits, transfer of technology, royalties, among others, obtained from the utilization of GRs or their derivatives, their application and subsequent commercialization" (Article 6).

In contrast to Peru, where the authority to grant access is dispersed among three entities, in Ecuador such responsibility lies exclusively with one entity. The Executive Decree No. 905 recognised the Ministry of the Environment as the competent national authority in charge of granting access and negotiating terms of distribution of benefits. This, however, changed in 2016 with the adoption of the Organic Code of the Social Economy of Knowledge, Creativity and Innovation, which transferred such competence to the National Institute of Biodiversity - the so-called INABIO – (Article 69), which until today lacks clearly defined rules of procedure for this task.

The access procedure is spelled out in the Executive Decree No. 905 and is primarily based on Decision 391. It begins with the submission and analysis of the access request before the competent national authority. In order to add transparency to the process, the Decree ensures the publicity of the request in order to give third parties the opportunity to oppose it (Article 18). Although a single entity is in charge of granting access, different government agencies (including bodies dealing with indigenous rights, intellectual property rights, endangered species, among others) are supposed to participate and provide their opinion in the analysis of the request (Article 21). Once the resolution that grants access has been issued, the competent national authority shall negotiate the terms of the access agreement with the user (Articles 25 to 30). According to the Decree No. 905, the contract shall contain clauses relating to the participation of local researchers, reporting obligations, monitoring and compliance with the terms of the agreement. Notably, along with the contract, users are required to provide a guarantee (of 5 per cent for non-profit users and of 10 per cent for profit-seeking users of the estimated cost of the project) in favour of the competent national authority (Article 31). Transfer of material is subject to the conclusion of an Agreement of Transfer of Material between the user and an ex situ conservation centre and subject to the approval of the Ministry of the Environment (Article 45).

The Executive Decree No. 905 also contains provisions relating to traditional knowledge, referred to as 'intangible component'. While recognising indigenous peoples' property rights over their traditional knowledge (Article 6), it requires the user to present a plan for obtaining the prior and informed consent of the holder of the intangible component associated to the GRs (Article 20). This is to be followed by the conclusion of an agreement between the community and the user, which is to be considered as an annex and condition of validity to the access agreement (Article 34).

Finally, in 2015 the Ministry of the Environment adopted the Ministerial Agreement 034 which contains a procedure for the conclusion of framework agreements for research on GRs for "exclusive scientific purposes". The procedure is shorter than the access procedure

---

<sup>10</sup> These views were shared by Lenin Nuñez and Diego Inclan of the National Biodiversity Institute and Ricardo Andrade and Wilson Rojas of the Ministry of the Environment in interviews conducted in March 2018.

contained in the Executive Decree No. 905; however, it also provides for the involvement of a national support institution in the research activities (Article 5). The request for a framework agreement shall be firstly approved by INABIO, while the agreement is to be signed by the user and the Ministry of the Environment (Articles 9 and 13). This agreement has a fixed-term period of three years, which could be extended up to five years (Article 14). In practice, this special regulation has facilitated the conclusion of several framework agreements on generally defined research programmes, which are supposed to incorporate, within the scope of that agreement, future specific projects that could emerge in the course of research activities.<sup>11</sup>

After the ratification of the Protocol, no further regulation has been adopted. According to a press release of the INABIO, the Ministry of the Environment and the National Secretary for High Education, Science, Technology and Research are in the process of developing a new regulation that is supposed to introduce procedural changes aimed at streamlining access procedures in conformity with the Nagoya Protocol.<sup>12</sup>

## 5 Final assessment and conclusion

In sum, Ecuador's and Peru's ABS regulations have their roots in Decision 391. The Andean Decision provides for the main substantive requirements of ABS, in line with the Protocol, namely the prior and informed consent of the provider country and the mutually agreed terms. On the other hand, the two national regulations continue to reflect -and they are supposed to continue to reflect- the regulatory approach of Decision 391, according to which the state retains the stronger bargaining power in ABS negotiations. In this regard, rules and procedures have been set out in both countries with the overall objective of protecting the interests of the provider country and of local and indigenous communities, while the determination of the rights of users is still absent. In this context, users' negotiation capacity is confined to the distribution of benefits as many clauses of the access contract are pre-established by the current regulation. From the institutional point of view, by delegating the power to grant access to different executive agencies, Peru has attempted to decentralize the ABS system, while keeping the function of designing ABS laws and policy with a central authority. In contrast, in Ecuador, the ABS procedure is centralized on one national authority, while a different authority has been appointed for the conclusion of framework agreements for non-commercial research. While in Ecuador no legislation has been adopted following ratification of the Protocol, in Peru the new proposal of ABS regulation seeks to harmonise national legislation with the Protocol, at least formally. However, it introduces ambiguous definitions that may impede achieving the legal certainty required by the Protocol. The biggest challenge that Ecuador and Peru have ahead of them is to find the way to harmonise, through national legislation and practice, the Nagoya Protocol and the CAN Decision 391, which are both binding in these countries.

### References

J. Caillaux, M. Ruiz, B. Tobin, *El Regimen Andino de Acceso a los Recursos Genéticos: Lecciones y experiencias*, Sociedad Peruana de Derecho Ambiental, 1999.

Ecuador, Constitution of 2008.

---

<sup>11</sup> Views expressed by Diego Inclan of the National Biodiversity Institute in interviews conducted in March 2018.

<sup>12</sup> See: <http://inabio.biodiversidad.gob.ec/2019/01/30/16-protocolo-de-nagoya-en-operacion/> (accessed 8 August 2019).

- Ecuador, Executive Decree No. 905, National Regulation on the Common Regime on Access to Genetic Resources in application of the Decision 391 of the Andean Community of Nations, 2011.
- Ecuador, Ministry of the Environment, Ministerial Agreement 034, Norms governing the procedure for the conclusion of framework agreements for accessing generic resources, 2015.
- Ecuador, National Institute of Biodiversity (press release), <http://inabio.biodiversidad.gob.ec/2019/01/30/16-protocolo-de-nagoya-en-operacion/> (accessed 8 August 2019).
- Ecuador, Organic Code of the Social Economy of Knowledge, Creativity and Innovation, 2016.
- Decision 391: “Common Regime on Access to Genetic Resources”, adopted by Parties to the Commission of the Cartagena Agreement in 1996.
- M. Gomez Lee, La Comunidad Andina frente al reto del acceso a los recursos genéticos y la distribución de beneficios, *Oasis* 17, 2012.
- Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, 2010.
- Peru, Act establishing the regime for the protection of the collective knowledge of indigenous peoples related to biological resources, 2002.
- Peru, Supreme Decree 003 - 2009 containing the Regulation for Accessing Genetic Resources, 2009.
- Peru, Ministerial Resolution 205 – 2019 containing the draft Regulation for Accessing Genetic Resources and their Derivatives.
- L. Silvestri, Conservación de la diversidad genética en el Perú: desafíos en la implementación del régimen de acceso a recursos genéticos y distribución de beneficios, *Revista peruana de biología* 23 (1), 2016.
- M. Ruiz Muller, Es necesario un nuevo marco jurídico para la bioprospección en la región andina? Breve revisión crítica de la Decisión 391, *Serie de Política y Derecho Ambiental* No. 14, 2003.