Shipping Policy Hackathon - Team 4 Submission

Overview

❖ **Scope:**

The following document focuses on Ecuador's import policies for biological parts, DNA/RNA and microbes. In addition, for microbial policy review, we will focus on the human and agricultural parts.

❖ **Policy Summary: provide a summary of the policies related to your scope.**

Ecuador ratified the Convention on Biological Diversity (CBD), which one of the main objectives of this treaty concerns the facilitation of the access to biological genetic resources.Nevertheless, there are other regulations that were issued later that include clauses that are not consistent with this provision of the CBD; such as the Andean Decision 391 and its Regulation to the common regime on access to genetic resources. Both legal instruments contain protectionist regulations and procedures that are so complex that blocks access to genetic resources in place to facilitate it, in contravention of the CBD.

In this context, the policies established for the importation of nucleic acids (DNA / RNA) are controlled by different public entities in the country, which represent long processes to obtain these biological products. Currently the name of DNA or RNA does not appear as a product within the legal framework of Ecuador, but as a by-product derived from a genetic material. The route of obtaining nucleic acids is carried out with processes for diagnostic or research purposes.

With respect to policies for the entry of non-genetically modified microorganisms into Ecuador, they have established a clear process for samples for research purposes for agricultural and clinical use, which were previously absent. The recent incorporation of these regulations has established a roadmap for synthetic biologists wishing to import commercial strains and samples from other laboratories. However, Ecuador still has no legal entities that regulate the use of microorganisms in other areas recognized by the customs like bioremediation, aquaculture, and others.

Overall, the complex process of importing and exporting genetic and biological resources within the Andean community and the absence of legal bodies for all applications related to microorganisms have delayed the development of synthetic biology in Ecuador.

❖ **Methods of research: describe how you identified policies (this can be brief).**

In different official portals (https://www.gob.ec/tramites/lista, https://www.agrocalidad.gob.ec/39798-2/, https://www.controlsanitario.gob.ec/) and through an internet browser, the search included the keywords: "import", "Ecuador" and/or the type of biological material, "genetic resource", "nucleic acid" or "microorganism". The search results were filtered according to their relevance with the objective of the following review, verifying the current status of the regulations and whose definitions or glossary of terms are consistent with the type of biological material.

❖ **Table of Policies:**

Policy Name	Country / Region	What biological materials?	What kinds of shipping	Limits	Relevant policy bodies	Other Notes	Link to details of policy
Executive Order 905 Regulation to the Common Regime on Access to Genetic Resources Reglamento al régimen común sobre acceso a los recursos genéticos	Ecuador	Genetic resources and their by-products	Import/ Export	It only applies in Ecuador	Ministry of the Environment of Ecuador	Art. 33. The entry and exit of genetic resources and their derived products from the country may only be carried out under the norms and conditions approved by the Ministry of the Environment as National Environmental Authority, taking into account the provisions of the different international agreements to which the State is a party and which apply to the present regulation.	https://www.gob.ec/sites/default/files/regulations/2018-09/Documento_Reglamento_regimen_comun_sobre_acceso_recursos_geneticos.pdf
COMEX Resolution N° 029-2017 Nomenclature of designation and codification of goods of Ecuador Resolución COMEX N° 029-2017 Nomenclatura de designación y codificación de mercancías del Ecuador	Ecuador	Nucleic acids and microorganisms	Import	Do not apply to Genetically Modified Organisms (GMOs) and viruses.	Ministry of Production, Foreign Trade, Investments and Fishing Foreign Trade Committee	**Custom tariff number** Nucleic acids and their salts 2934.99.30.00 Culture yeast 2102.10.10.00 Cultures of microorganisms: 3002.90.10	https://www.produccion.gob.ec/wp-content/uploads/2019/06/RESOLUCI%C3%93N-COMEX-020-2017.pdf

Organic Health Law Ley Orgánica de Salud	Ecuador	Biochemical Diagnostic Reagents (Nucleic Acids)	Import	Do not apply to research reagents	Ministerio de Salud Pública (MPS) Ministry of Public Health	Art. 137. Medicines in general in the manner provided for in this Law, biological products, (....) and biochemical diagnostic reagents, manufactured in the national territory or abroad, are subject to obtaining health registration. its importation, commercialization, dispensing, and sale.	https://www.salud.gob.ec/wp-content/uploads/2017/03/LEY-ORG%C3%81NICA-DE-SALUD4.pdf https://www.salud.gob.ec/wp-content/uploads/downloads/2013/09/reglamento_sobre_el_material_gen%C3%A9tico_septiembre_2013.pdf
ARCSA Resolution 16 - 2020 - LDCL Technical standard for importing drugs, medical devices Norma técnica importación medicamentos, dispositivos médicos	Ecuador	Diagnostic reagents (DNA)	Import	Only apply for donated reagents	Agency for the Regulation and Control of Phytosanitary and Animal Health	Substitute technical regulation to authorize the importation by exception and importation by donation of medicines, biological products, medical devices, and biochemical and diagnostic reagents.	https://www.salud.gob.ec/wp-content/uploads/2020/08/resolucion_arcsa-de-0016-2020_ro_7700710487001597330757.pdf
		Microorganisms, eukaryotic cells, ... products obtained by recombinant DNA or hybridomas, propagation of microorganisms in embryos or animals.	Import	Do not apply to GMOs	Agency for the Regulation and Control of Phytosanitary and Animal Health AROCALIDAD	The research protocol that uses the microorganisms must be approved by the ARCSA	

Resolución Nº 143 - Manual of procedures for the registration and control of biological control agents, plant extracts, mineral preparations, semiochemicals and related products for agricultural use Manual de procedimientos para el registro y control de agentes de control biológico, extractos vegetales, preparados minerales, semioquímicos y productos afines de uso agrícola	Ecuador	Microorganisms (fungi, bacteria, protozoa and viruses) to which are attributed to an effect on pest control	Import	Do not apply to GMOs	Agency for the Regulation and Control of Phytosanitary and Animal Health	A list of pathogenic microorganisms that are not allowed to be imported is necessary	http://www.fao.org/faolex/results/details/es/c/LEX-FAOC197467/

Analysis

❖ Impact of policies on synthetic biology work:

In 1992, Ecuador ratified the Convention on Biological Diversity (CBD), which proposed innovative concepts and principles in the area of genetic and biological resources. One of the main objectives of this treaty concerns the facilitation of the access to biological genetic resources. Furthermore, the positive and negative effects in the Cartagena Protocols biological security and Nagoya Protocol on access and benefit sharing.However, there are other regulations that were subsequently created that are not consistent with this provision of the CBD and have a negative impact on synthetic biology work.

Decision 391 of the Andean Community, and its Regulation to the common regime on access to genetic resources, establishes a protectionist mechanism based on access contracts between the parties, an extension of the definition of sovereignty of the states and the recognition of the participation not only of the State, but also of the indigenous communities and of the providers of biological resources; they pose a high complexity in the procedural area. Likewise, the 2008 Constitution of the Republic has introduced provisions that instead of contributing to the regulation of access to these strategic resources, hinder their treatment.

All of the above, instead of facilitating access, constitutes an obstacle that discourages users of genetic resources. Furthermore, the development of research in the biotechnological area (including synthetic biology) in the region is hindered, since both the import and export of genetic and biological resources between the countries that are signatories to the CBD and Decision 391 hinder exchange and collaboration in scientific research.

Currently, policies on the use of genetic material in Ecuador as resources for the development of synthetic biology are deficiently regulated in legal and technical terms. In 2015, the definition of Synthetic Biology (SynBio) was established for the first time based on expert judgment and other existing definitions, where it was concluded that non-living entities resulting from SynBio were not subject to the Cartagena Protocol on Biosafety. These entities include parts such as DNA molecules, and products (results of SynBio processes).

With respect to policies for the entry of non-genetically modified microorganisms into Ecuador, although they can be simplified, they have established a clear process for samples for research purposes for agricultural and clinical use, which were previously absent. The recent incorporation of these regulations has established a roadmap for synthetic biologists wishing to import commercial strains and samples from other laboratories.

❖ Critique of policy and practices:

Import laws specifically for DNA/RNA have not been enacted in Ecuador. However, there are laws with general concepts such as "Genetic Material" or "Diagnostic Reagents" that include such biological products. The problem with this terminology is that it causes confusion since its definitions are very broad and by not specifying the products to which it refers, it can even lead to subjective interpretations that affect the release of the product from customs.

In the case of microorganisms, as described above, the procedures within the regulations can become complex due to ambiguous definitions that are not in line with international standards. The current import procedure requires the researcher to interact with several governmental entities, causing the procedure to become delayed and sometimes it can cause the deterioration of the product. In Ecuador, since there are no regulations for each application that can be given to microorganisms, the process can be interrupted indefinitely if the authorities do not agree on the regulations under which the product can be imported, sometimes making it impossible to import microorganisms.

Proposal

One of the most important problems in Ecuadorian legislation is the ambiguity in the political language and the general terms used to describe specific biological products. That said, iGEM Ecuador proposes to implement and organize scientific committees to clarify and specify this terminology for future resolutions of import laws. Taking this measure is important since there are biological products (such as DNA, RNA and biological parts) that are not supposed to be a health risk, but their association in general terms includes other products that indeed represent a risk and, therefore, hinder their process of import.

In addition, it would be important that bioethical committees were included in new legislative resolutions for the implementation of biological products that have not been considered so far but are necessary for research and innovation. This measure could help to import products that are currently unknown to customs and therefore are often not released from the warehouse.

To solve the problems described above in the importation of microorganisms, it is necessary that internationally standardized definitions such as those described by the Food and Drug Administration (FDA) be used within the regulations, to avoid confusion between the importer and exporter. One way to make the import procedure faster is to accept import procedures from other regulatory entities belonging to the Andean Community of Nations, which corroborate the characteristics of the microorganisms and affirm that regionally established regulations are complied with. Taking into account that it is necessary to implement regulations that contemplate all applications of microorganisms, it is possible to extrapolate existing regulations to applications that lack one, as long as the microorganisms to be imported are not genetically modified and do not represent a pathological risk to the country.

Regarding the importation of microorganisms, Ecuador could base a reorganization of its regulations based on the one already existing in Colombia. In which, microorganisms can be imported through three considerations: commercial purposes, scientific research purposes and others (zoos, among others). When microorganisms are imported for research purposes, it is not necessary for the applicant to obtain a non-CITES permit and only in the case of bioremediation purposes, the applicant must have the certification of a specialized laboratory that verifies that they are not living modified organisms (LMO).