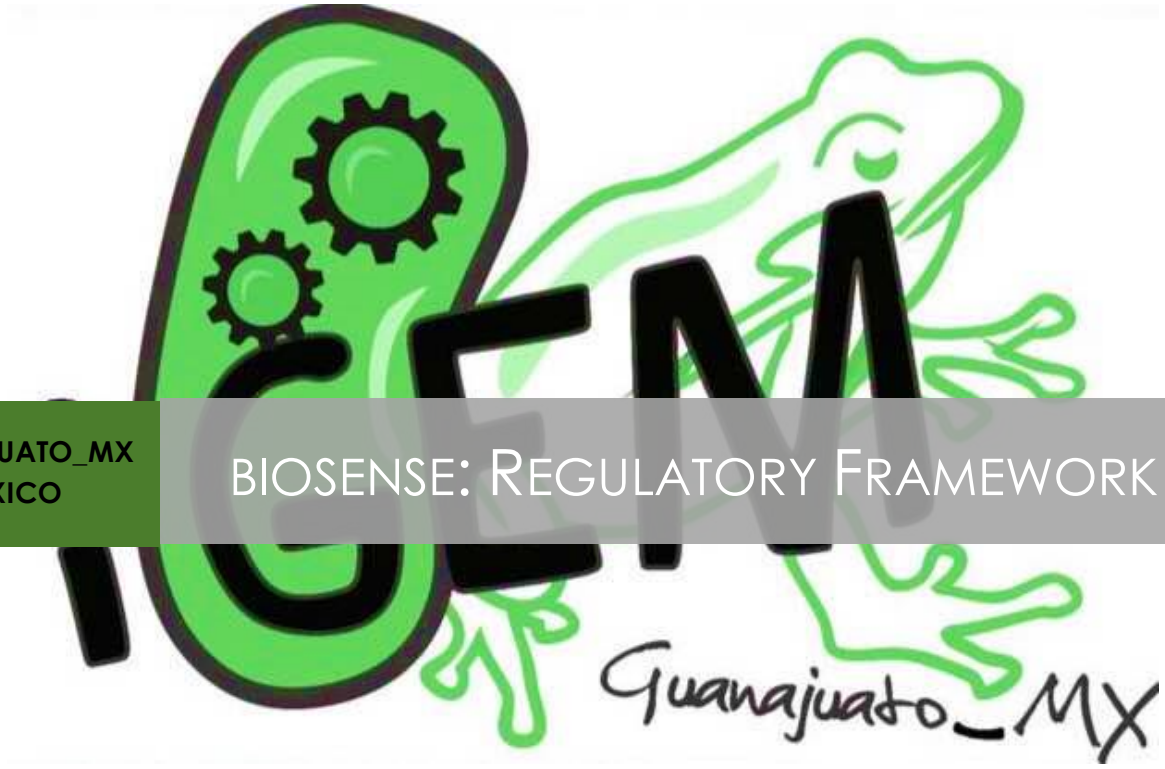

GUANAJUATO_MX
MÉXICO

BIOSENSE: REGULATORY FRAMEWORK

Regulatory Framework

During the development of our project we decided to go a bit further and learn more about the legislation required in our country for the creation of this type of technology in case this project ever goes out of the Lab. In order to do this we decided to work alongside law students to see how Mexico is doing in terms of the regulation of products derived from biotechnology and synthetic biology.

Introduction

Through the last couple of decades, science has made some major steps in the development of new technologies that have changed the way we study and understand the world that surrounds us. Biotechnology, one of these modern technologies, has given a lot of new discoveries that have helped humanity in a lot of areas, but it has also led to raise new ethical, political and legal concerns due to all of the new possibilities that have arised in the last decade of genetic engineering.

Historically it is known that science and technology are always a step ahead of public policies given the fact that new laws and regulations are always changing as a result of these advances. In the development of our project we were not an exception and we found ourselves with trouble at first, to locate our project in the current regulations regarding the matter of the creation of new biotechnological products. This was not an easy task because even though there is some regulation of Biotechnology in our country , there is no precedent projects that resemble our project. Nonetheless even though we managed to locate our project, we ran into more problems, from simple aspects such as terminological gaps, to more complex aspects like what are known colloquially as legal gaps which are the absence of regulations regarding the specific course.

With all these problems that we faced when wanting to analyze the regulatory framework of our project that today, is just an idea that is on par with the most advanced discoveries in modern biotechnology, we were forced to raise several questions that come from the lack of adequate norms like: What happens in reality?; What happens to all of those scientist who wish to take their research outside of the lab but are stopped by an outdated law or by outdated law enforcers?.

Given this it is important to mention that this work is not intended to critique the legal system of our country, but unfortunately these are realities that we faced during the development of our project. Our purpose is to raise awareness about the feasibility and biosecurity of our project and how it is hard to encompass some biotechnological products due to the non specialized laws that may apply in our country.

In this paper we will address each of the regulatory systems with modern biotechnology interference at a national and international level in order to achieve an easy understanding of the current situation in our country.

We will focus on the regulatory mechanisms that directly or reflexively cover the concerning aspects of genetically modified organisms and the use of these products in humans which is the main purpose of our project.

In order to address this we will **study each of the legal systems by their "hierarchical order",** beginning with our Mexican Constitution, continuing with the the international legal framework, federal laws and lastly, with the Official Mexican Standards which are the ones that really answer the question of how to actually carry out projects in our country.

Our Project

In order to understand what we will be referring to as "project" throughout this paper and before starting to talk about the legal systems that frame our work we must first establish, for legal purposes, what we understand by it.

The main objective of our project consists in the elaboration of a biopatch that is capable of detecting and killing pathogenic bacteria that are commonly found on skin burns, this with the use of biosensors that are engineered to produce antimicrobial peptides in the presence of pathogens.

Hence, beyond the fact that the essence of our project (which main goal is to work with a genetically modified bacteria for medical purposes) is not covered or regulated by Mexico's Ministry of Health, we could say that it is regulated and done under the rules established by the Mexican official standards that are applicable in generic aspects such as the manufacturing of drugs .

Given this and since the main purpose of the project is the improvement of human health and the proper medical term for the project did not fit into any law by its active principle, we consider it sufficient, although not ideal, to frame our project as a **pharmaceutical product**. It is intended for its use in human beings as a form of mitigation, treatment, prevention or diagnosis of a particular disease or symptoms that modifies the physiological system for the benefit of the person to whom it is administered.

Therefore it is under this criteria that we will make the analysis of the current regulations in our country.

Political Constitution of the United Mexican States

It is needless to say that all aspects of which laws and other international regulatory norms, including the principles under which the mexican state adopts an international treaty of any kind, are set out in this document. It is for this reason why it is important to name this document, and even though studying our constitution is not the purpose of this work it is important to highlight the articles that establish the essential bases for official Mexican Norms and laws which will be the guiding principle of our study:

> Article 3°, establishes in a general way, the foundations of education, determining that the state should support scientific and technological research;
>
> Article 4 °, talks about the right to health and the main law in which our project revolves, the General Health Law.

It is Important to emphasize, as already stated, that the Constitution, along with each and every one of its 136 articles, sets the basis for the entire legal system of our country . And if the proper awareness of this is taken we can see how from a single *term* or *sentence* inside our constitution a lot of rights, obligations and laws could be derived. Therefore by

establishing only two precepts from the constitution in our work we don't mean to say that these two are the only ones that support and regulate this investigation and our project, but rather that these two articles are the only ones that manage to do so in a direct and almost textual manner.

International Law

Our country is part of a large number of international organizations, through which it has signed over the last decade, an endless number of international treaties that create a comprehensive policy framework on issues of global importance, including biotechnology.

It is Important to clarify that for the purposes of our study, we limit ourselves to only some of the essential international instruments that regulate biotechnology. This clarification is made because our project has a lot of interference on aspects of human health, which, in an international context, is regulated through the World Health Organization (WHO) and its agreements and specific committees, of which Mexico is part of.

Convention on Biological Diversity

This agreement was established and adopted by international governments on December 29, 1993 with the main objective of setting out commitments for maintaining the world's biodiversity. The convention has 3 main goals which are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the use of genetic resources.
The importance of this instrument is that it opens for the first time the outlook for biodiversity and recognizes that all types of ecosystems, species and genetic resources should be used in a proper way. In addition, it is the lynchpin for one of the most important treatises on biotechnology.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity

It is an international treaty of an environmental nature which aims to protect the "transfer, handling and use of genetically modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological biodiversity, taking also into account risks to human health [...] ".
The importance of this treaty is that it establishes the principles of the regulation of biotechnology. However, we found that in reality and for the purposes of our work it does not have great interference because, as it is established in Article 5 of this treaty, this Protocol does not apply to the transboundary movement of living modified organisms which are used as pharmaceuticals for humans.
In this manner, although this treaty fails to determine the regulatory framework of our project it does helps us to begin demarcating it.

Nagoya Protocol

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 is an international treaty that sets a reference to the fair and equitable sharing of benefits arising out of the utilization of genetic resources. It entered into force on 12 October 2014 in our country, and it obliges all states and countries that have ratified it to take a series of measures regarding the utilization of genetic resources.

In the case of our project we consider this international instrument as well as the *Nagoya Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol* on Biosafety as a regulatory "framework" that, even though it does not establishes a proper regulation of it and it does not addresses essential parts of our project, it does helps us to delimit it.

National Scope

Once we enter the legislation aspects of our country, we find ourselves with a large number of laws that revolve around this matter. And it is for this reason , why we think it is important to mention that there is a regulation in our country for genetically modified organisms, but the problem is that a huge part of these are focused mostly on agriculture and on the progress on improving food production and not that much of it is focused on the fabrication of medicinal or pharmaceutical products for human use.

The responsible of this are, in a broad manner, the Ministry of health through the Federal Commission for the Protection against sanitary Risk (COFEPRIS), and other organizations like the General Health Council and institutions like the Mexican Social Security Institute, the National Autonomous University of Mexico and the National Polytechnic Institute that aid in the creation of applicable norms.

General Health Law

This law of federal nature established in 1984, has suffered innumerable reforms over the years in order to be consistent and updated with national and global social reality , and is one of the largest in our political system because it regulates all the aspects related to public health in our country. It gives rise to a host of regulations and Mexican official standards, several of which will be analyzed later to frame our project.

In its article 222 Bis, it establishes the legal regime of Biotech drugs in México and it states that all biotech drugs should obtain the proper sanitary registration, as long as they provide and meet the requirements that demonstrate the quality, safety and efficacy of the product.
It also notes that all applicants for bio comparable biotechnological drugs should support their application with biocompatibility studies.

Also in its Chapter XII BIS titled “Biotechnological Products” through the course of 3 articles, it gives the main guidelines for their development in medicine and tells us that a biotechnological product are those foods, additives, raw materials, health products, etc., that involve the use of living organisms or parts of them by means of traditional breeding or genetic engineering. It also establishes that the Secretary of Health is the only faculty able to grant the permits and authorizations for products that are destined for use or human consumption.

As we can see, this law only provides the general guidelines for creating all the relevant legislation which will be discussed below.

Biosafety Law of Genetically Modified Organisms

This law which was published in the Official Federal Gazette on March 18, 2005 aims to regulate the activities of experimental release, commercialization, marketing, import and export of genetically modified organisms. It is important to denote this law because it helps us to frame our project by giving us the general guidelines of the processing that should be applied to genetically modified organisms that are of public health concern in our country. It is established in this law that the whole process for the marketing , commercialization or use of GMOs for medical or Bioremediation purposes requires an authorization granted by the Ministry of Health.

An application should be submitted to the already named secretariat in order to receive a proper authorization. This application should be accompanied by a scientific and technical risk assessment report on the potential health risk that could arise from the use or consumption of the Genetically Modified Organism. This report should include aspects regarding its safety in order to ensure that they do not cause risk or harm to the health of the population.

The secretariat may grant or deny an authorization whenever the proper requirements are not met or when the object of study demonstrates that it poses a danger to human health.
It also sets out the guidelines for the packaging and identification of genetically modified organisms and establishes the obligation for the competent organizations to issue and publish a list of the GMOs that have been granted a permission and the ones that did not receive a permit.

As we can see, this law provides us with the specific information required for the use of GMOs with medical purposes and also the necessary procedures for its authorization. However it still leaves a gap on what are the necessary aspects required for its manufacturing under the Official Mexican Standards.

Regulation for Health Supplies

These regulations derived from the General Health Law, aim to control health medical supplies, as well as activities related to them. It specifically tells us what is considered a biotech or biopharmaceutical compound and it defines it as “any substance that has been produced by molecular biotechnology, which has pharmacological therapeutic, preventive or rehabilitative effect and has been identified by its physical, chemical and biological properties that make it eligible to be used as an active principle in a biotech drug”

It also establishes the pharmacovigilance to which these drugs need to be subject to , and it refers it as the science that tries to collect, monitor, investigate and evaluate information on the effects of drugs, biological products, medicinal plants and traditional medicines, with the objective of identifying the possible adverse reactions they could have, in order to prevent damage in patients. This monitoring should also allow a clear identification of the relevant biotech drug by establishing its manufacturer, name and active compounds.

Official Mexican Norm 257-SSA1-2014 In Biotechnological Drugs Materia

This official norm whose origin comes from the General Health Law, but is originally derived from the previously mention regulation is considered essential for the proper regulatory framework of Biotechnological drugs that we have studied so far. This Norm's main goal is to establish : 1) the guidelines for assessing the information given in the application for registering medicines;2) the criteria under which the Health Ministry will regulate this drugs; 3) the requirements for its manufacturing and 4) the procedure for authorizing the protocols for such drugs.

This is the norm that will give us the proper specifications to bring to reality a biotechnological drug.

It is stated in this Norm that the drug must be submit to a control of its fabrication, where it will ensure its own quality and the validation of its fabrication process. Asides from this the protocolos for the creation of the medicines should be authorized by the Secretary of health.

All of this laws and norms have helped us to establish as a general regulatory framework in order to understand how feasible, legal and safe our project would be to society. It is important to say that due to the stage at which the project has been developed , these are the norms that would be necessary to mention in order to do our work properly, however we are are aware that if this project would ever come to reality we would need to include other rules regarding the criteria for the implementation of research projects in human beings like the one established in the Official Mexican Standard NOM012-AAS3-2012 , and also a proper study on the packaging and marketing requirements necessary to meet the rules in the law of intellectual property with its respective patents and trademarks.

Conclusion

In order to give out a conclusion, we must first understand that even though the legislation of genetically modified organisms may seem deficient, we do find laws that regulate this aspects of biotechnology in our country. However the problem that we faced when trying to establish a regulatory framework for our project was that it was hard to frame it in a particular law due to its specific characteristics and because there hasn't been any project of this kind in our country

Nonetheless after the study of all the laws of Biotechnological interference we could conclude that our project is feasible and can be done under our Legal System as long as the proper risk assessment studies and proper authorizations by the Secretary of health proof that our bio patch is biocompatible, and safe for its use in humans.

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