

# LEGAL PLAN

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IGEM TEC-CHIHUAHUA

# iGEM Tec-Chihuahua 2022

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## 1. General Analysis

Agriculture is the most significant productive sector in Mexico. Pests and diseases are an enormous concern for agricultors. They destroy up to 40 percent of global crops and cost \$220 billion of losses (FAO, 2021).

Chili is one of the most important crops not only in Mexico but worldwide (Pilches, 2017). Its production generates a large economic spill. Mexico is the number 1 exporter worldwide of chilis and peppers. Chihuahua is the leading state in its production. In 2020, 732 thousand tons were produced, equal to 5,011 million pesos. This gives a job to more than 12,000 producers and 30 million laborers (La Jornada, 2021; Vite, 2019).

*Phytophthora capsici* is an oomycete that infects the plant through haustoriums by entering the cell. Once it is inside, it releases effector proteins. These inhibit the plant's natural defense and consume its intracellular nutrients. *P. capsici* remains on the soil as oospores for more than 2 years. It spreads thanks to surface water, attacks plants during the different stages of their life, and infects plants in 2-3 days (Babadoost, 2016).

*P. capsici* causes root, stem, and fruit rot of the host, as well as foliar blighting and damping-off. The severity of this disease has shown annual losses of up to 100% on chili crops (Nabor-Romero *et al.*, 2020). The oomycete attacks eggplant, tomato, cucumber, zucchini, pumpkin, watermelon, melon, green beans, apples, potatoes, and more. Agrocapsi (the "Project") has proposed a solution based on synthetic biology.

## 2. Current Status

The application of chemical elements in the environment affects human and other living organisms' health. Team iGEM Tec-Chihuahua 2022 (the "Team") has generated an integrated legal plan focusing on chili harvest. With the intention of safeguarding the fundamental rights of society, its people, and our project as an enterprise (in the future).

In general terms, it can be said that this legal plan contains three main aspects:

- I. The protection of society's human right for the environment and health.
- II. The technical analysis of the safety issues to be observed.
- III. The protection and projection of the project as a company.

## 2.1 Current situation of pesticides at the international level

The World Health Organization (“WHO”) is currently aiming to address the global pesticide phenomenon. It is responsible for international health access and public health matters. Also, promotes the improvement of environmental conditions and the fight against several diseases.

Insecticides, herbicides, and biofungicides are pesticides that protect crops from insects, weeds and diseases. Diseases caused by fungi or oomycetes are common in plants. Hence, fungicides are used to control the disease during the development of the crop. To increase their productivity and reduce their damage (Ravichandra, 2018).

Nevertheless, pesticides generate a great health risk. These can be toxic to humans and cause a variety of health effects (Lushchak *et al.*, 2018; Syafrudin *et al.*, 2021). The exposure to these products is a threat for people who come into contact with them at:



Home



Work



Garden

Each pesticide has different properties and toxic effects. The toxicity of a pesticide depends on the product, its function and other factors. Its effect depends on the dose (the amount that the person is exposed to). Since it is spreaded into the environment, its distribution should be controlled (Lushchak *et al.*, 2018).

It is clear that there exist some concerns about the health effects of pesticides in diverse countries. Due to this, severe measures are being taken to prevent them. Health consequences can be avoided by choosing the least toxic pesticide.

The most vulnerable groups are those who use these items and reside nearby. For this reason, the WHO and the Food and Agriculture Organization of the United Nations have evaluated the different risks of pesticides and developed the International Code of Conduct on Pesticide Management. Its purpose is to establish the best practices for

the proper management of pesticides throughout their life cycle, both in production and disposal (WHO, 2018).

## 2.2 Current situation of pesticides at the national level

Pesticides have influenced the development of agriculture. It is a solution that prevents crops from being affected by insects, weeds, and other pests. The toxicity of these products is intrinsic. They must be regulated to minimize the risks derived from their use, without affecting productive activities. Mexican authorities aim to guarantee the quality and efficacy of the pesticides used. Because due to their toxic nature it is necessary to prevent risks on the environment and people's health.

Pesticides poses a risk by causing poisoning, congenital anomalies, miscarriages, reproductive issues, liver damage, blood issues, cancer, and more. The WHO estimates that the use of pesticides is linked to about 37,000 cancer cases annually, but further research is needed.

Since a number of States employ pesticides, they have accumulated over time in various ecosystems. People can exhibit physical changes on their skin, nausea, and headaches, which are brought on by consuming food tainted by pesticides. According to the WHO, inadvertent pesticide poisonings are thought to be the cause of about a million deaths annually.

According to experts, exposure to the same material in the field or through food consumption directly causes toxicity in humans. One of the primary ways people are exposed to pesticides and waste is through the environment. Because pesticide residues are often thrown on the soil, where they can be carried by rain and eventually reach water sources that are for human use. Pesticides also come into touch with insects, animals, fruits, and vegetables through the air, but the highest risk comes from direct exposure (Al-Taai, 2022).

The manner of contact will affect how hazardous pesticides are to humans. Inadequate handling of chemicals or a lack of protection are to blame for this. Both chronic and acute conditions exist:

**Table 1.** Chronic and acute symptoms provoked by agrochemicals.

| Chronic symptoms   | Acute symptoms   |
|--|--|
| <ul style="list-style-type: none"><li>• Cancer</li><li>• Organ damage</li><li>• Mutation</li></ul> | <ul style="list-style-type: none"><li>• Allergic Reactions</li></ul> |

On the other hand, these consequences also have an impact on soil, air, and biodiversity loss. According to Mexican officials, the substances are capable of spending some time in the atmosphere. According to WHO and FAO, there are several factors that indicate a pesticide's toxicity since those that are classified as having chronic toxicity are those that cause illnesses as what was described above is a result of it.

México has banned 20 pesticides since 1991 (DOF, 1991) and in 2016, the registration of 7 more pesticides that belonged to the Stockholm Convention and Rotterdam Convention were canceled. These both agreements belong to the legal framework of Mexico. Several of the pesticides belonging to the Stockholm Convention have been annulled. The federal administration has issued statements informing that pesticides will go through more rigorous and complex controls for the limitations of their use. To carry out this, the Federal Law was published.

Last but not least, there are a number of contentious instances in Mexico involving the use of pesticides, such the cases of Endosulfan, LindanE, and "Agricultural Heart in Mexico."

**Table 2.** Mexican cases regarding the use of pesticides.

| Pesticide | Endosulfan  | LindanE   | Agricultural Heart in Mexico   |
|-----------|---|---|--|
| Context   | In the Stockholm Convention of 2011 Endosulfan was globally banned. However it continued to be internally commercialized in Mexico. Thanks to an agreement of COFEPRIS and commercialization companies until August 2016. Endosulfan was introduced to various crops in 1950 and used intensively against a variety | The revocation process by the National Service of Agrifood Health, Safety and Quality (SENASICA) was made in 2009 with the aim to prohibit LindanE worldwide. But, the registration company delayed the process until 2016. | Sinaloa (México State) faced a situation known as "Agricultural Heat of Mexico" regarding the use of non-biodegradable pesticides with ingredients like Heptachlor epoxide (exceeds the maximum limit recommended in the FAO/WHO Environmental Standard). These infiltrate in different ways to water and cause serious situations of contamination for terrestrial and marine ecosystems. |

|       |  |  |  |
|-------|--|--|--|
|       | of insects in agriculture.   |  |  |
| Risks | <p>It was found that various effects are presented in some species of bees (individuals and colonies). Some of them were the reduction of olfactory abilities, memory and brain skills reduced.</p> <p>The use of its product is seen as the main PAPs in crops of the Valley of Culiacán. It presents acute toxicity where the dangerousness is indicated by the Pesticide Action Network and is banned by 75 countries (Negatu <i>et al.</i>, 2021).</p> | <p>This caused pollution in soil, water, biota and sediments by means of the discharge of toxic substances.</p> <p>Around 2,464,000 tons of pesticides are discharged on agricultural land in the State. This amount is estimated. There are no exact measurements of discharges and their effects on surface currents and bays, apart from physical-chemical, bacteriological and nutrient contamination. Which can be seen in Laguna Santa María. The presence of 14 pesticides and molecules of heptachlor epoxide, p,p-DDE, enderlin and aldrin, whose contents are lower than other coastal systems in the region (Oyinloye <i>et al.</i>, 2021).</p> |  |

As stated in the previously mentioned cases, it is substantial to adopt regulations regarding the application of active ingredients and products. In addition, the utilization and disposal of organic agriculture and the use of biofertilizers, bioinsecticides, and biofungicides must be implemented. Likewise, it is necessary to develop more technology for the creation of new biodegradable formulas, in order for pests and diseases of the region to diminish and not affect ecosystems.

### 3. Applicable Law and Competent Authorities.

The Project requires permits, authorizations, licenses and/or concessions for its legal and correct operation. The Team has analyzed

applicable law and competent authorities that could have interest in the Project. Since that the Project involves agriculture, health and the environment matters. The following authorities may have interest or jurisdiction in the Project:

**Table 3.** Institutions for Project development.

| Institution   | Function   |
|---|--|
| SADER: Agricultural and Rural Development Secretariat (Secretaría de Agricultura y Desarrollo Rural)          | Entitled to regulate and monitor the primary economic sector. Meaning the collection, extraction and transformation of natural resources with little or no human intervention. The Project is directly linked to SADER, because it is related and focuses on Chili harvesting and cultivation. |
| SEMARNAT: Environmental and Natural Resources Secretariat (Secretaría de Medio Ambiente y Recursos Naturales) | Entitled to monitor and combat climate change and preserve ecological balance. The Project is directly subordinated to this Secretariat, since environmental contingencies prevention and response may be created and executed at any time.  |
| SSA: Health Secretariat (Secretaría de Salud)   | Entitled to monitor, prevent and improve public health, through diverse agencies and institutions.   |

Additionally, an agency interest analysis has been made as follows:

**Table 4.** Agencies for Project development.

| Institution   | Function   |
|---|--|
| COFEPRIS: Federal Commission for the Protection against Sanitary Risks (Comisión Federal para la Protección contra Riesgos Sanitarios), | Part of SSA, is entitled to monitor and issue pesticides sanitary authorizations. The foregoing is specially relevant for the Project due to the release of pesticides to the environment. |
| CIBIOGEM: Intersecretarial Biosecurity Commission for Genetically Modified Organisms (Comisión  | Integrated by federal SADER, SEMARNAT, SSA, Federal Education, Federal Taxing, Federal Economics and CONACYT Directors, is entitled to monitor, determine and issue national               |



|   |   |
|---|---|
| Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados)                                 | GMOs biosecurity policy. The Project, in very general terms, is indirectly regulated by such agencies, due to the isolation and liberation processes.   |
| SENASICA: National Food Safety and Quality Service (Servicio Nacional de Inocuidad y Calidad Agroalimentaria) | Decentralized Administrative Body of SADER, which main function is the protection of agricultural resources from pests and diseases, as well as the regulation and promotion of systems to reduce risks of food contamination and its agri-food quality, reason why it is intrinsically related to the Project's objective (eradication and/or inhibition of a pest that directly attacks agriculture). |

Federal authorities and agencies indicated hereinabove are regulated by the following laws and regulations:

**Table 5:** Laws and regulations for Project development.

| Law/Regulation   | Description   |
|--|---|
| CPEUM: Mexican Federal Constitution (Constitución Política de los Estados Unidos Mexicanos)  | The Constitution contains the principles and objectives of the nation. It establishes the existence of organs of authority, their powers and limitations, as well as the rights of individuals and the ways to make them effective.   |
| LGEEPA: General Ecological Balance and Environmental Law and its Regulation (Ley General de Equilibrio Ecológico y Protección al Medio Ambiente y su Reglamento) | The law establishes the minimum budget for the preservation and restoration of ecological balance, as well as the protection of the environment, in the national territory. Likewise, it establishes a general framework on information and participation in environmental matters and responsibility for environmental damage. |
| LGS: General Health Law (Ley General de Salud y su Reglamento)   | The General Health Law has established the guidelines and principles for scientific and technological research that must be followed to achieve public health.  |
| LGIE: General Import and Export Law (Ley General de Importación y Exportación)   | It establishes the fees that, according to the classification of the merchandise, will  |

|  |  |
|--|--|
|  | determine the General Import and Export Taxes.   |
| RISAGARPA: Agricultural and Rural Development Secretariat Domestic Regulation (Reglamento Interior de la Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación) | It is in charge of exercising what is established in the Organic Law of the Federal Public Administration, as well as the regulations, decrees, agreements and orders of the President of the United Mexican States.   |
| RMRA: Record, Authorization, Import and Export Pesticide and Plant Nutrient Certificate Regulation (Reglamento en Materia de Registros, Autorizaciones).                               | Decree amending, adding and repealing several provisions of the regulation regarding registries, import and export authorizations, and export certificates of pesticides, plant nutrients and toxic or hazardous substances and materials.   |
| LBOGM: GMO's Biosecurity Law (Ley de Bioseguridad de Organismos Genéticamente Modificados)   | It regulates the confined use activities, experimental release, pilot program release, commercial, marketing, import and export of genetically modified organisms, with the in order to prevent, avoid or reduce the possible risks that these activities could cause to health or the environment and biological diversity or animal, plant and aquaculture health. |
| RCIB: CIBIOGEM Regulation (Reglamento de la Comisión Intersecretarial de Bioseguridad de los Organismos Genéticamente Modificados)   | It regulates the organization and functioning of the Intersecretarial Commission of Biosafety of Genetically Modified Organisms.   |

The project involves the Human Rights of society at large (healthy environment). Hence, it is important to take into consideration international treaties as:

Cartagena Protocol: Cartagena Protocol on Biosafety to the Convention on Biology Diversity.

However, it is not possible to rely exclusively on specific legislation to control the practices of the Project in an effective manner, along with the relevant areas of interest and competence between the many laws and

authorities. As a result, the Legal Team Section found itself in need of discovering a solution to this scenario through the study of NOMs.

#### 4. NOMs

NOMs are the legally required regulations that determine the norms and principles that must be followed when producing or providing goods or services that might endanger people, animals, or the environment as a whole. In the area of health control and sanitary promotion, these regulations refer to the information pertaining to the rules, specifications, attributes, guidelines, characteristics, or requirements applicable to a product, process, system, service, or production method or operation, which must be fully covered by the goods and services marketed in the nation for commercialization. The primary benefit of these standards is their cross-disciplinary nature, i.e., the ability of several agencies to work together to regulate AdHoc procedures for processes involving various agencies.

The Mexican government, which is in charge of detecting the dangers, evaluating them, and issuing a NOM required to avert them, also develops NOMs through technical committees composed of members of several government departments. These guidelines enable governmental organizations to set up measurable standards to reduce health hazards. Official Mexican Standards ("NOMs") have also been issued and will be mentioned below.

A NOM establishes three key aspects in general:

- I. The description of the procedure or service.
- II. The requirements and procedures that must be followed.
- III. The authorities in charge of overseeing compliance.

We considered diverse norms regarding industrial safety regulations involved to operate safely, which are the following:

Table 6. NOMs to operate a company safety

| Norm                                   | Name                               | Objective   |
|--|------------------------------------|---|
| <a href="#">NOM-001-S<br/>TPS-2008</a> | Buildings, premises and facilities | Establish the safety conditions of the buildings, premises, facilities and areas in the work centers for their proper functioning and conservation, in order to prevent risks to workers. |

|  |  |   |
|--|--|---|
| <a href="#"><u>NOM-002-STPS-2000</u></a> | Fire prevention, protection and fighting | Establish the minimum safety conditions that must exist for the protection of workers and the prevention and protection against fires in the workplace.   |
| <a href="#"><u>NOM-010-STPS-1999</u></a> | Chemical contaminants                    | Establish measures to prevent damage to the health of workers exposed to chemical contaminants in the work environment, and establish the maximum permissible limits of exposure in workplaces where chemical substances are handled, transported, processed or stored that, due to their properties, concentration levels and exposure time, are capable of contaminating the work environment and altering the health of workers. |
| <a href="#"><u>NOM-017-STPS-2008</u></a> | Personal protection equipment            | Establish the requirements for the selection, use and management of personal protective equipment, to protect workers from agents in the work environment that can harm their health.   |
| <a href="#"><u>NOM-019-STPS-2004</u></a> | Safety and hygiene commissions           | Establish the guidelines for the constitution, organization and operation of the safety and hygiene commissions in the workplace.   |
| <a href="#"><u>NOM-021-STPS-1994</u></a> | Reports on occupational hazards          | Establish the requirements and characteristics of reports of occupational risks that occur, for the labor authorities to keep national statistics on them.  |
| <a href="#"><u>NOM-026-STPS-2008</u></a> | Colors and safety signs                  | Establish the requirements in terms of colors and safety and hygiene signs, and the identification of risks due to fluids carried in pipes.   |
| <a href="#"><u>NOM-028-STPS-2004</u></a> | Safety in chemical processes             | Establish the elements of a management system to organize safety in critical processes and equipment that handle dangerous chemical substances, in order to prevent major accidents and protect people, work centers and their environment from damaging.   |
| <a href="#"><u>NOM-030-STPS-2009</u></a> | Preventive health and safety services    | Establish the functions and activities that must be carried out by preventive health and safety services at work to prevent accidents and work-related illnesses.   |

As a socially responsible company, it is necessary to consider the risks when using our product through the security measures suggested by the official Mexican standard.

Table 7. NOM regarding the risks that come with the use of pesticides and fertilizers.

| Norm                                   | Name                       | Objective  |
|--|----------------------------|--|
| <a href="#">NOM-003-S<br/>TPS-1999</a> | Pesticides and fertilizers | Establish safety and hygiene conditions to prevent the risks to which workers who carry out agricultural activities of storage, transfer and handling of phytosanitary or pesticide inputs and plant nutrition or fertilizer inputs are exposed. |

## 5. Product Classification

The Product is initially classified as a Biofungicide. Due to its properties, as stated in the in the Product Classification Section of the “Risk Analysis and Evaluation”, and its characteristics, the Product is preliminary classified as a Biofungicide (Botanical Pesticide). Pesticides (a genus related to biofungicides and botanical pesticides) must be registered with COFEPRIS for hygienic purposes.

Taking into consideration what was previously mentioned, it is planned to submit a Technical Request of Information to COFEPRIS. For the Team to determine how the Project can be categorized and if it is regarded as a pesticide or like a botanical pesticide. For the purposes of this document, the Technical Request for Information will act as a direct line of communication with the appropriate authorities for the proper identification of the Project. The findings of such authority have not been considered for the purposes of this document since this has a response period defined by such authority of roughly 180 business days.

## 6. Permits, Licenses and Authorizations

For the realization of the Project it's necessary to be formally authorized by the Mexican Government. The project (Whether nationally or internationally) has to be registered after the matching agency in order for it to be legally commercialized.

### 6.1 Classification

In Mexico the term “biofungicide” is not used by the authorities. For the purposes of this Project, classifications issued by COFEPRIS will be used.

COFEPRIS divides these types of products into either “Pesticides” or “Plant nutrients”. The Project fits into the category of “Pesticides” defined as a substance destined to control any species which may interfere with agricultural production.

More specifically, the Project approaches the term of botanical pesticide within the terms that are established in the Article 2, Subsection XL of the RMRA. Regarding the requirements established for the permits of its authorization, trafficking, and exportation, these differ from other pesticides because of its classification as a specific kind of pesticide and the components that it is made of.

## 6.2. Pesticide registration.

The permits related with the pesticide registration held by COFEPRIS, are addressed in the Article 10 of the RMRA. Where all the necessary and the general documentation for registration application are established, which matches with all necessary documents required with article 7, that need to be filled in a pre-established format that contains all necessary information that can be also found in the Article 12 of the same regulation. It is important to mention that these procedures are dependent on each other, so the expedition of some permits are necessary for the obtainment of others. Likewise, the requirements established by the Pesticide Registration Process proposed by the Environmental Protection Agency (EPA) of the United States were also considered.

### 6.2.1 Sanitary Authorization for Implementation of Pesticides and Plant Nutrients

First, Sanitary Authorization for Implementation of Pesticides and Plant Nutrients should be obtained at COFEPRIS. This authorization allows producers to produce and pack the pesticide to, subsequently, either use it or sell it. To process this Authorization, the applicant has to provide the request correctly filled after the agency, attaching also the following documents (which are required by COFEPRIS), each with a copy:

- 1 Payment Receipt for the amount specified by Federal Tax Fee Law (Ley Federal de Derechos).
- 2 General Report on machinery and personnel required for producing the Project.
- 3 Capacitation plan for personnel who will handle substances which make up the product.
- 4 Security Form including the toxic substances from the Project.
- 5 The establishment's technical information card, according to the Technical.
- 6 Guide and the Helping Formats of the Application.
- 7 Workers' Health Surveillance Program, which includes details on the place where the pesticide will be produced, health risks for the worker, the POE's identification, biosafety measures for production, identification card number and the corresponding doctor's signature.

### 6.2.2 Sanitary Registration of Botanical Pesticides

The Sanitary Register of Botanical Pesticides, which is issued by COFEPRIS and regulated in Article 12 of the RMRA, must be obtained jointly with the Sanitary Authorization for Implementation of Pesticides and Plant Nutrients, where in this article states that the following requirements must be submitted:

- PLAFEST application required by COFEPRIS, proof of entitlement payments for the amounts established in the Federal Law of Rights of Rights), a document that accredits the personality of the promoter and a letter of access to the physicochemical information of the composition of the product.
- The technical requirements are divided into six aspects:

Table 8. Requirements for the registration of pesticides.

|    |  |
|----|--|
| 1. | The common and scientific names of the plant or plants from which the botanical extract was derived must be specified in a report. Additionally, the formulation of the substance, the aspect related to the usefulness of pesticides in an agricultural, domestic, urban, and |
|----|--|

|    |  |
|----|--|
|    | livestock use, forest organization, and finally the general information of the areas where the product is to be applied and controlled and the type of pest, specifying the common name, genus, and species of the pest.   |
| 2. | In order to determine a material's qualities, including its physical condition, its density must be established for a liquid substance or its specific weight in the case of solid substances.   |
| 3. | Physical properties that are appropriate for the type of formulation include information on the product's moisture content, wettability, foam persistence (if applicable), suppressibility, dry particle size analysis, average micron particle size present, emulsion stability, redistribution properties, and how the key ingredients are obtained. |
| 4. | Regarding toxicological data, a research on acute oral and dermal toxicity in mammals must be applied, and a technical opinion on biological efficacy provided by SADER in the name of the applicant who is ostensibly registering the product must also be filed.   |
| 5. | When it comes to information on storage stability, a stability study must demonstrate what will happen if the product is exposed to certain situations, such as high temperatures. Additionally, a paper outlining the Project's impact before and after, with a focus on estimating how long its impact will persist.                                 |
| 6. | Finally, the Product's draft label is currently enforceable and complies with all relevant Mexican official rules, as well as, EPA requirements.   |

### 6.2.3 Unrestricted Selling Certificate

The producer shall submit an application for the expedited issuance of the Unrestricted Selling Certificate, as required by Articles 39 and 40 of the RMRAIE, after obtaining the Sanitary Registration of Botanical Pesticides and the Sanitary License for the Establishment. According to this legislation, a pesticide must have a valid registration in order to be sold inside the national territory. This certificate's validity period is one year, beginning on the day of its expedition. After COFEPRIS, the following information should be included in the application for this certificate:

- The applicant or his or her legal representative should fill out and sign the official form as appropriate.
- In addition to the document designating authorized individuals to hear and receive documents in the event that the applicants are companies, the document confirming the legal personality (POA) of the



applicant, which may include the Reference Number from the Accredited Members Registry (Registro de Personas Acreditadas), is also required.

- Payment Receipt authorized by SHCP
- Valid Sanitary Registration number
- The Sanitary License Number or the copy of the Operation Permit.

COFEPRIS has to authorize the expiration of the unrestricted selling within the next three business days after the day of application. In case that the application submitted is incomplete or doesn't meet the requirements, it shall be prevented from completing the missing information. If those documents are not submitted in time after the issue, the request must be rejected.

### 6.3 Pesticide's Exportation

The legislation from the request will be filled by the applicant when the application for the certificate to export the Project is done. However a different request must be filled by the applicant and diverse information will be required. Once the fields are covered, there will be awarded a certificate specialized in the matter of exportation.

- It will be asked to the equal authority the Export Only Pesticide Registration, where in the equal files as the Sanitary Registration of Botanical Pesticide are required except for annexing the technical components of the pesticide to be carried out for the export of the product (In this case, the technical components required for the botanical pesticide need to be precise due to the fact it's for the nearest to method the character of the Project).
- Once the applicant acquires this permit, she or he might be capable of requesting COFEPRIS for the Exportation Certificate. This may also be legitimate for one year. For this, COFEPRIS calls for the identical files from the Unrestricting Selling Certificate, without the exception of the Exclusive Exportation Pesticide Registration as opposed to the Sanitary Registration of Botanical Pesticides. Also, the applicant shall include the country of destination and a letter of commitment by the applicant where it is promised that the product won't be sold within national territory.

## 7. Risk Analysis and Assessment

To the extent that projects involve the use of CRETIB substances (as defined in LGEEPA as corrosive, reactive, explosive and/or biologically infectious substances), it is necessary to plan and implement measures to ensure the safety and health of those previously contacted during and after the development, production, storage, distribution and application of the Project.

This analysis has been developed in depth in the Appendix "Risk Analysis and Assessment".

## 8. Entrepreneurship area entailment

Due to the fact that the project is closely linked to the area of entrepreneurship. It is necessary to provide legal reinforcement to the Project as a product and as a company.

In order to provide a legal reinforcement to the Project as a product, an opinion on the trademark has been prepared to determine the viability of protection before the Mexican Institute of Industrial Property (Instituto Mexicano de la Propiedad Intelectual "IMPI"). This authority is responsible for receiving, resolving, and registering trademarks in our country, so it's necessary to make a preliminary analysis to analyze the possibilities of registering the trademark. The report is focused on determining whether "Agrocapsi" has any problems with its trademark application before the Mexican Institute of Industrial Property (Instituto Mexicano de la Propiedad Intelectual "IMPI"). Said report concluded with the premise that it is fully feasible for its submission and protection and that the application could be submitted at any time, as required.

For more information, please refer to: "Agrocapsi Trademark Report".

It's also important to take into consideration the safety measures necessary for the product to enter the market. For the above, it is necessary to take into account the rules that regulate the packaging and the labels that will sustain the products of the brand. This information can be consulted in the "Risk Analysis and Assessment". As for the protection of the Project as a company, it is important to take into consideration that, in order to start operations and/or apply for permits, the Project must be supported as a company constituted under Mexican law. This constitution allows the Project to enter into contracts, to carry out administrative procedures, among other things. In this case, it has opted for the creation of a S.A. de C.V. due to the fact that, in the future, the Project will require large investments for its development and circulation in the market. In Mexico, the S.A. de C.V. is the most versatile company in terms of investment and corporate governance, since it allows the main shareholders to have more effective control of the company when expanding to third-party investments. In order for the product to be in full capacity to enter the market at any given moment,

a format of an Incorporation Act before a Notary Public has been formulated, which can be appreciated in the "Incorporation Format Introduction". Finally, in order to provide means to assess the entry of the product into the market, without it being binding on any of the parties, a Letter of Intent has been prepared. This document has as its objective the correct valuation in terms of the purchasing value of a competitive market. For more information, please refer to "Letter of Intent".

## 9. Human Practices entailment

The security of personal information is another crucial factor to take into account. For this reason, we developed a document called "Privacy Notice" that was used to conduct interviews with producers, agronomists, institutions, and experts in various fields. In this document, we pledge to treat the information we've collected with care and respect.

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