

# MINISTRY OF AGRICULTURE AND LIVESTOCK

## MINISTERIAL AGREEMENT No. 109

### THE MINISTER OF AGRICULTURE AND LIVESTOCK

#### CONSIDERING:

**That,** Article 13 of the Constitution of the Republic of Ecuador, establishes, among the rights of Good Living: *“Individuals and communities have the right to safe and permanent access to healthy, sufficient and nutritious food; preferably produced locally and in harmony with their diverse cultural identities and traditions. The Ecuadorian State will promote food sovereignty”*;

**That,** Article 154(1) of the Constitution of the Republic of Ecuador states: *“In addition to the powers established by law, the ministers of state are responsible for: 1 Exercise the leadership of the public policies of the area under its responsibility and issue the administrative agreements and resolutions required for its management (...)”*;

**That,** Article 227 of the Constitution of the Republic of Ecuador states: *“Public administration is a service to the community that is governed by the principles of effectiveness, efficiency, quality, hierarchy, de-concentration, decentralization, coordination, participation, planning, transparency and evaluation”*;

**That,** Article 334(4) of the Constitution of the Republic of Ecuador states: *“The State shall promote equitable access to the factors of production, for which purpose it shall: (...) 4. Develop policies to promote national production in all sectors, especially to guarantee food and energy sovereignty, generate employment and added value”*;

**That,** Article 130 of the Organic Administrative Code states: *“The highest administrative authorities have normative competence of an administrative nature only to regulate the internal affairs of the organ in their charge, except in those cases in which the Law provides this competence for the highest legislative authority of a public administration. Regulatory competence over the actions of individuals must be expressly conferred by law.”*;

**That,** Article 8 of the Organic Law of the Food Sovereignty Regime states: *“The State, as well as individuals and communities, shall promote and protect the use, conservation, qualification and free exchange of all native seeds. The production, certification, processing and marketing activities of seeds for the promotion of agro-biodiversity will be regulated by the corresponding law. Germplasm, seeds, native plants and ancestral knowledge associated to the above mentioned constitute patrimony of the Ecuadorian people, consequently they will not be object of appropriation under the form of patents or other modalities of intellectual property, in accordance with Article 402 of the Constitution of the Republic.”*;

**That,** Article 33 of the Organic Law on Agrobiodiversity, Seeds and the Promotion of Sustainable Agriculture – LOASFAS (for its acronym in Spanish), states: *“(…) Only*

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*cultivars registered as such in the National Register of Cultivars may be submitted to the seed certification process. (...)*";

**That,** Article 127 of the Organic Law Reforming the Comprehensive Criminal Code reformed the Third General Provision of the Organic Law on the Comprehensive Prevention of the Socioeconomic Phenomenon of Drugs and on the Regulation and Control of the Use of Catalogued Substances Under Supervision, adding the following text: *"Non-psychoactive cannabis or hemp, understood as the cannabis plant and any part of that plant, with a delta-9-tetrahydrocannabinol (THC) content of less than 1% on a dry weight, is excluded from the catalogued substances subject to control, and its regulation is the responsibility of the National Agricultural Authority"*;

**That,** the Fifth Transitory Provision of the Organic Law Reforming the Comprehensive Criminal Code establishes: *"The National Agrarian Authority shall issue the regulations referred to in article 127 of this law within 120 days after the entry into force of this law"*;

**That,** by means of Executive Decree No. 487 dated August 21, 2018, the Constitutional President of the Republic of Ecuador, Lenín Moreno Garcés, appointed Mr. Xavier Lazo Guerrero as Minister of Agriculture and Livestock;

**That,** by means of Ministerial Agreement No. 028 dated February 27, 2020, Article 6 of the Organic Statute of Organizational Management of Minister of Agriculture and Livestock processes was reformed, establishing the mission of this Ministry, as follows: *"We are the leading institution and executor of public agricultural policies, we promote productivity and health of the agricultural sector, with environmental responsibility through the development of organizational and commercial technical capabilities of agricultural producers at the national level with emphasis on small, medium and family and peasant agriculture, contributing to food sovereignty"*;

**That,** by means of memorandum No. MAG-SPA-2020-1175-M dated October 14, 2020, the Undersecretary of Agricultural Production sent the preliminary Ministerial Agreement to issue the Regulations for the import, sowing, cultivation, harvest, post-harvest, storage, transportation, processing, commercialization and export of non-psychoactive cannabis or hemp and hemp for industrial use, for review and subsequent subscription; and the Technical Report, which states: *"It is recommended that this ministerial agreement is signed in order to comply with the delegation stipulated in the fifth transitory of the organic law reforming the Comprehensive Criminal Code"*; and,

In exercise of the above-mentioned constitutional, legal and regulatory powers and based on the foregoing considerations:

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## AGREES TO:

### ISSUE REGULATIONS FOR THE IMPORT, SOWING, CULTIVATION, HARVEST, POST-HARVEST, STORAGE, TRANSPORT, PROCESSING, COMMERCIALIZATION AND EXPORT OF NON-PSYCHOACTIVE CANNABIS OR HEMP AND HEMP FOR INDUSTRIAL USE

#### TITLE I GENERALITIES

#### CHAPTER I SCOPE AND DEFINITIONS

**Article 1.- Purpose:** The purpose of this Regulation is to establish the rules for the import, sowing, cultivation, harvest, post-harvest, storage, transport, processing, commercialization and export of Non Psychoactive Cannabis or Hemp and Hemp for Industrial Use in Ecuador, as purely agro-industrial products; and, consequently, to establish the difference in a clear and precise way between Psychoactive Cannabis and Non Psychoactive Cannabis or Hemp, through the National Agrarian Authority as the governing body of public policies in agricultural matters.

**Article 2.- Scope:** The dispositions contained in this Regulation are of obligatory application in all the national territory, for the import, sowing, cultivation, harvest, post-harvest, storage, transport, processing, commercialization, and export of non-Psychoactive Cannabis or Hemp and Hemp for Industrial Use.

**Article 3.- Definitions.** - For all purposes derived from this Regulation and in order to understand and comprehend its contents, the following definitions shall be used:

- 1. Storage Area:** Area enclosed in a property or group of properties authorized by the National Agrarian Authority where collection, packing, storage, distribution and export activities are carried out.
- 2. Cultivation Area:** Area delimited in a property or group of properties that on the basis of a license is enabled by the National Agrarian Authority to carry out the activities of primary production of Non Psychoactive Cannabis or Hemp plants, or Hemp for Industrial Use
- 3. Post-Harvest Area:** Area delimited in a property or group of properties enabled by the National Agrarian Authority where the licensees authorized to cultivate carry out activities such as drying to give thermal treatment to the harvested biomass and packing.
- 4. National Agrarian Authority:** It is the Ministry of Agriculture and Livestock, competent State Portfolio for the regulation and control of Non Psychoactive Cannabis or Hemp and Hemp for Industrial Use.
- 5. Biomass:** Any organic material from the Non-Psychoactive Cannabis Plant or hemp, or hemp for industrial use that is made up of all parts of the plant after being harvested and transformed by drying or other processes, including organic residues or waste. The living plant is not considered Biomass.

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6. **Good Agricultural Practices (GPAs):** They comprise practices oriented to the improvement of conventional methods of production and handling in the field, with emphasis on the prevention and control of hazards for the safety of the product.
7. **Good Manufacturing Practices (BPM):** A set of preventive measures and general hygiene practices in the handling, preparation, processing, packaging and storage of by-products for human or animal use, in order to ensure that they are manufactured under adequate sanitary conditions and thus reduce potential risks or hazards to their safety.
8. **Cannabinoids:** Those chemical substances that link with the cannabinoid receptors of the body and the brain, and they can be classified in Phytocannabinoids, Endocannabinoids and synthetic Cannabinoids, among the most common Phytocannabinoids we have: CBD (Cannabidiol), CBN (Cannabinol), CBG (Cannabigerol) and THC (Tetrahydrocannabinol).
9. **Cannabis:** Any herbaceous plant of the Cannabis genus, which includes the tops, flowering or fruiting, seeds, leaves and any plant material from the same, whatever name it is called.
10. **Non Psychoactive Cannabis or Hemp:** Plant of the species Cannabis and any part of this plant, including its seeds and all its derivatives, extracts, cannabinoids, terpenes, isomers, acids, salts and salts of isomers, either in cultivation or in biomass, which content of THC is lower than 1% in dry weight. Non Psychoactive Cannabis or Hemp, its parts and its derivatives, are not controlled substances, and therefore are excluded from the Organic Law of Integral Prevention of the Socioeconomic Phenomenon Drugs and its Regulation. When in this Regulation only Hemp is mentioned it will be understood that it refers to Non Psychoactive Cannabis.
11. **Psychoactive Cannabis:** Plant of the species Cannabis and any part of this plant, including its seeds and all its derivatives, extracts, cannabinoids, terpenes, isomers, acids, salts and salts of isomers, either in cultivation or in biomass, which content of THC delta-9-tetrahydrocannabinol is equal or bigger than 1% in dry weight.
12. **Hemp for Industrial Use:** Plant of the Cannabis species belonging to varieties of Non Psychoactive Cannabis or Hemp, including its seeds and all its derivatives, extracts, cannabinoids, terpenes, isomers, acids, salts and salts of isomers, which production purposes are industrial, including plant material, whether stems, grain, biomass, or other foliage material that has not been processed whose THC content is less than 1% of dry weight.
13. **Harvest:** It is understood as the harvest of Non Psychoactive Cannabis or Hemp, or Hemp for Industrial Use, the partial or total harvest of the plant, whether it is a culm, flowering or with fruit from the Non Psychoactive Genetic Plant.
14. **Cultivate:** Set of cultivated plants that are distinguishable by certain morphological, physiological, cytological, chemical or other characteristics determined by genetics; significant for agricultural purposes and that when reproducing sexually or asexually maintain their own characteristics. The term "variety" when used to indicate a cultivated variety is equivalent to "cultivate".
15. **Non Psychoactive Cannabis or Hemp Derivatives:** Consists of oils, resins, tinctures, raw extracts or other innovations resulting from technological development, obtained from Non Psychoactive Cannabis or Hemp, with a THC content of less than 1%, including, cannabinoids, isomers, acids, terpenes, salts and isomer salts, which are used or intended to be used as raw material for the manufacture of the Finished Product. Since Non-Psychoactive Cannabis Derivatives or Hemp are not Finished Products, under no circumstances may they be sold or transferred in any way in health food stores, pharmacies, commercial establishments or similar for use or direct human or animal consumption.

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16. **Hemp Derivatives for Industrial Use:** Products coming from the vegetal material of Hemp for Industrial Use, from its stems, seeds, seed husks, woody material, or other foliar material, like biomass, with THC content lower than 1°/0 in dry weight, destined for Industrial Purposes.
17. **Non Psychoactive Cannabis or Hemp Cuttings:** Fragment of the plant (stem, branch or bud) of Non Psychoactive Cannabis or Hemp, with the ability to root and replicate the initial plant, through grafting or its introduction into the soil.
18. **Facilities for the Production of Derivatives:** Property or group of properties authorized by the National Agrarian Authority, where Non Psychoactive Cannabis Derivatives or Hemp or Hemp Derivatives for Industrial Use are produced.
19. **Hemp Grain:** Hemp seed for human or animal use or consumption, commercialized as a finished product.
20. **Licensee:** Legal entity constituted or domiciled in the Republic of Ecuador, authorized by the National Agrarian Authority to develop one or more activities described in these Regulations.
21. **Legal Entities:** are those described in Article 5 of these Regulations.
22. **Seedlings:** Individuals derived from a process of sexual or asexual propagation destined to the establishment of cultures for commercial or research purposes.
23. **Pollen:** These are the male sex cells of flowering plants. They are formed inside the stamens and once they are mature they are released with the purpose of reaching the female part of a flower of the same species and making possible the fertilization of the oocyte.
24. **Standard Operating Procedures (SOPs):** Written procedures that describe and explain how to perform a task step-by-step to achieve a specific goal.
25. **Processing:** It is a set of transformation stages applied to raw materials of agricultural, livestock, fishing and forestry origin, ranging from their benefit or first value addition, to the instance that generates final products with a higher degree of processing.
26. **Finished Product:** Products obtained from the manufacture of Non Psychoactive Cannabis or Hemp Derivatives, to be commercialized or distributed as a product for human or veterinary use or consumption and that has a sanitary registration, sanitary notification or the license that applies according to the type of product according to the Ecuadorian legislation. Among them, but not limited to the following: processed foods, dried flowers, beverages, food additives, food supplements and supplements, cosmetics, homeopathic products, medicines, medical devices, processed natural products for medicinal use and veterinary products.

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27. **National Registry of Licensees:** This is the National Registry to be created and maintained by the National Agrarian Authority, which shall contain the information regarding licensees and those licenses that have been issued, suspended, revoked or that have not been renewed, according to the conditions established in these Regulations.
28. **Seed:** It is the one obtained from the fruit, after the fertilization of the flower, the fruits or parts of these, as well as part of vegetables or complete plants destined to the reproduction and propagation of the different vegetable species, such as botanical seed, cuttings, grafts, rootstocks and material propagated in vitro; they contain genetic information and knowledge associated to it.
29. **Certified Seed:** Seed that has fulfilled the technical process of production and benefit, which ensures its genetic and physiological quality, purity and phytosanitary condition, as well as the verification of productivity, in accordance with LOASFAS and this Regulation.
30. **Non Psychoactive Cannabis Seed or Hemp or Industrial Hemp Seeds:** Propagation material of seeds, cuttings or any other vegetative part of the Cannabis plant that is used for planting and/or propagation and whose genetic content of THC is less than 1%.
31. **Applicant:** Legal person, legally constituted or domiciled in the Republic of Ecuador, that requests to the National Agrarian Authority, previous fulfillment of the legal and regulatory requirements, the concession of the License to be able to develop one or more of the activities described in these Regulations.
32. **THC:** It is the delta-9-tetrahydrocannabinol, cannabinoide of the Cannabis, psychoactive component and which is subject of regulation; other THC, such as the delta - 8, the THC a, or the THC b, are not subject to regulation.
33. **Traceability:** Possibility to trace a product in the different stages of the production, transformation and distribution chain, by means of registered identifications, such as the batch code.

**Article 4.- Classification of the Cannabis Plant:** For the purposes of these Regulations, the Cannabis Plant is classified as Non Psychoactive Genetic Plants and Psychoactive Genetic Plants.

Non Psychoactive Genetic Plants are those that contain less than 1% THC of their dry weight.

Those plants that contain a percentage equal to or greater than 1% of THC of their dry weight are considered Psychoactive Genetic Plants and are not under the jurisdiction of the National Agrarian Authority; therefore, they are not under these regulations.

In case of detection of Psychoactive Genetic Plants, the National Agrarian Authority will immediately inform the regulating entity to intervene, according to the attributions established in the Organic Law of Integral Prevention of the Socioeconomic Phenomenon of Drugs.

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**Article 5.- Authorized Persons for the Development of Activities:** Those legal persons, cooperatives, associations or communes, universities, legally constituted and/or domiciled in the Republic of Ecuador, as the case may be, duly registered in the National Registry of Licensees and authorized by the National Agrarian Authority through the respective license, which may develop one or more activities provided for in these Regulations.

### CHAPTER II SEEDS AND CUTTINGS

**Article 6.- About the import of Non-Psychoactive Cannabis or Hemp Seeds, or Hemp Seeds for Industrial Use, or Non-Psychoactive Cannabis or Hemp Cuttings:** Without prejudice to the provisions of the Organic Law of Agrobiodiversity, Seeds and Promotion of Sustainable Agriculture (hereinafter LOASFAS) and its Regulations, the import of Non-Psychoactive Cannabis or Hemp Seeds, or Hemp Seeds for Industrial Use, or Non-Psychoactive Cannabis or Hemp Cuttings, must be authorized by the National Agrarian Authority, which must issue the respective license, only if they have a concentrate lower than 1% of THC in dry weight and if they are going to be destined to the applicant's own sowing and cultivation or commercialized by other Licensees authorized to sow and cultivate them.

The Licensees that have a License for the Cultivation of Non-Psychoactive Cannabis or Hemp, or License for the Cultivation of Hemp for Industrial Use, will be able to import Seeds or Cuttings of Non-Psychoactive Cannabis or Hemp, or Hemp Seeds for Industrial Use, according to the case, as long as its final object is the industrialization or own use of its cultures and not its commercialization like seed or cuttings. The Licensees that take benefit of this exception will have to fulfill the established thing in the LOASFAS and its regulation.

The Licensees that have the License for Plant Breeding and/or Germplasm Banks and Research, in the same way, will be able to import Non Psychoactive Cannabis or Hemp Seeds or Cuttings, or Hemp Seeds or Cuttings for Industrial Use for the pertinent purposes as established in the LOASFAS and its regulations. They cannot commercialize seeds, cuttings or biomass, without first obtaining the corresponding license; otherwise all vegetative material must be eliminated once the productive cycle of the crop is finished.

The commercialization of Non-Psychoactive Cannabis or Hemp Seeds, or Hemp Seeds for Industrial Use, or Non-Psychoactive Cannabis or Hemp Cuttings to third parties who do not have the respective License for Non-Psychoactive Cannabis or Hemp Cultivation, or the License for Hemp Cultivation for Industrial Use, is prohibited.

**Article 7.- Production of Non-Psychoactive Cannabis or Hemp Seeds or Cuttings, or Hemp Seeds for Industrial Use:** Without prejudice to what is stipulated in LOASFAS and its Regulations, the production of Non-Psychoactive Cannabis or Hemp Seeds, or

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Hemp Seeds for Industrial Use, or Non-Psychoactive Cannabis or Hemp Seedlings, must be authorized by the National Agrarian Authority, which must issue the respective license, as long as the genetics of its plants have a THC concentrate lower than 1% in dry weight.

For this purpose, the Applicant must be registered in the National Registry of Licensees.

The commercialization of Non-Psychoactive Cannabis or Hemp Seeds, or Hemp Seeds for Industrial Use, or Non-Psychoactive Cannabis or Hemp Cuttings, to third parties who do not have a License for Non-Psychoactive Cannabis or Hemp Cultivation, or the License for Industrial Cannabis Cultivation, is prohibited.

Licensees who hold a License for Non-Psychoactive Cannabis or Hemp Cultivation, or a License for Industrial Hemp Cultivation, to produce and commercialize Non-Psychoactive Cannabis or Hemp Seeds or Cuttings, or Hemp for Industrial Use, must comply with the requirements set forth in the Licenses for the above activities.

**Article 8.- Control of first sowing:** Those Licensees that do not carry out validation tests under the provisions of LOASFAS and its regulations, must submit the results of the tests of the first harvest carried out by a laboratory authorized by the National Agrarian Authority, in which the percentage of THC in dry weight, for each imported variety, must be detailed. The first sowing and crop development will be supervised by the National Agrarian Authority and/or its associates.

### CHAPTER III SOWING AND PRODUCTION

**Article 9.- Authorization for Sowing:** Only Non-Psychoactive Cannabis or Hemp Plants, or Non-Psychoactive Cannabis or Hemp Seeds, or Hemp Seeds for Industrial Use, or Non-Psychoactive Cannabis or Hemp Cuttings may be sown, prior authorization issued by the National Agrarian Authority, which must expedite the respective license. For this effect, the Licensee must be registered in the National Registry of Licensees.

For the culture of the Hemp for Industrial Use the minimum extension of the Area of Culture must be of 5 hectares, which can be cultivated gradually according to the Plan of Agricultural Production (Annex 3) approved by the National Agrarian Authority.

For the cultivation of Non Psychoactive Cannabis or Hemp, the minimum extension of the Cultivation Area must be 5 hectares in open field and 2 hectares in greenhouse, which may be cultivated gradually according to the agricultural production plan, previously approved by the National Agrarian Authority.

The period in which the minimums detailed above will be fulfilled according to what is indicated in the agricultural production plan, cannot exceed 5 years counted from the first crop, which will be verified by means of inspections.



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Licensees with a License to Plant and Produce Non-Psychoactive Cannabis or Hemp Seeds, or Non-Psychoactive Cannabis or Hemp Cuttings, or Hemp Seeds for Industrial Use, must have a minimum Cultivation Area of 0.5 hectares.

The Licenses for Plant Breeding and/or Germplasm Banks and Research, will not be restricted to a minimum area of sowing, following the requirements established in the LOASFAS and its regulations.

**Article 10.- Additional sowings:** In case of increases of the Cultivation Area, the Licensee shall request to the National Agrarian Authority the extension of the respective License, before proceeding with the sowing in the additional area.

If it is verified that there are new non authorized crops, or a larger area than the authorized one, the National Agrarian Authority shall sanction the sowing, according to the provisions of these Regulations.

**Article 11.- About the Post-Harvest:** Once the harvest is done, the material must be transferred to the Post Harvest Area where the drying process will take place. The Post-Harvest Area must be located in a property authorized by the National Agrarian Authority within the cultivation license. Only operators with a cultivation license may carry out the post-harvest process.

The Licensee may not use the dried material without an analysis that demonstrates a THC content of less than 1%.

**Article 12.- Harvest Samples:** The Licensee shall request the National Agrarian Authority to take a sample once the post-harvest process is completed.

The sample must be kept by the inspector until it is handed over to the laboratories authorized by the National Agrarian Authority. Once the sample is analyzed, the Licensee must send the results to the National Agrarian Authority, which will authorize its use, within the framework of its License and these regulations, in case the result is less than 1% of THC in dry weight

**Article 13.- Excess of Limits:** In case that a harvest of Non Psychoactive Cannabis or Hemp, or Hemp for Industrial Use exceeds the limit established for the concentration of THC, the National Agrarian Authority will notify the competent Authority.

## CHAPTER IV PROCESSING

**Article 14.- Processing:** Processing of Non-Psychoactive Cannabis or Hemp is understood as obtaining any of the derivatives mentioned in the definition of Non-Psychoactive Cannabis or Hemp Derivatives.

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Applicants seeking to process Non-Psychoactive Cannabis or Hemp must obtain the License for Processing Non-Psychoactive Cannabis and Production of Non-Psychoactive Cannabis or Hemp Derivatives.

The License for Processing of Non-Psychoactive Cannabis or Hemp and Production of Non-Psychoactive Cannabis or Hemp Derivatives authorizes Licensees to acquire plant material of Non-Psychoactive Cannabis or Hemp, solely and exclusively from growers who have the respective License.

Licensees who have a License for the Cultivation of Hemp for Industrial Use and, who would like to obtain Non-Psychoactive Cannabis or Hemp Derivatives, from the seedless flower of Hemp for Industrial Use, must comply with all applicable requirements for Processing Non-Psychoactive Cannabis or Hemp Derivatives, and obtain the respective License.

Processing of Hemp Derivatives for Industrial Use does not require a license.

**Article 15.- Labeling:** Without detriment to what is established in the special rules on labeling, the labeling of the Non Psychoactive Cannabis or Hemp Derivatives imported or of national manufacture must contain:

- a) Name or trademark of the product.
- b) Denomination of the product.
- c) Batch identification.
- d) Type of Derivative.
- e) Net content.
- f) Licensee's full business name and address.
- g) List of components, with their respective specifications (when applicable).
- h) Country of product manufacture.
- i) THC percentage.

Non-compliance with the provisions of this Regulation regarding minimum labelling will be considered an infringement.

The requirements set out in this article do not apply to Finished Product for human or animal use or consumption, which shall be regulated by the competent authority.

## CHAPTER V COMMERCIALIZATION, IMPORT AND EXPORT

**Article 16.- Commercialization:** The producers of Non-Psychoactive Cannabis or Hemp, or of Non-Psychoactive Cannabis or Hemp Derivatives, or producers of Hemp for Industrial Use or of Hemp Derivatives for Industrial Use, that have obtained the corresponding Licenses for those activities, will be able to commercialize the Derivatives

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as raw material to process them in the local market or to export them, without necessity of obtaining additional Licenses for the commercialization or export of their products.

The commercialization of the Finished Product shall be regulated by the rules issued by the competent authority in the respective field.

**Article 17. - Importation of Non-Psychoactive Cannabis or Hemp Biomass, or Hemp Biomass for Industrial Use and/or Non-Psychoactive Cannabis or Hemp Derivatives and/or Hemp Derivatives for Industrial Use:** The import of Non-Psychoactive Cannabis or Hemp Biomass, or Biomass of Hemp for Industrial Use and/or of Non-Psychoactive Cannabis or Hemp Derivatives and/or of Hemp Derivatives for Industrial Use, manufactured abroad, may be done with previous authorization granted by the National Agrarian Authority to the Licensees that have the License for the Processing of Non-Psychoactive Cannabis or Hemp and Production of Non-Psychoactive Cannabis or Hemp Derivatives.

Non-Psychoactive Cannabis or Hemp Derivatives manufactured abroad must fulfill the same requirements established in these Regulations for Non-Psychoactive Cannabis or Hemp Derivatives processed or manufactured in Ecuador.

The authorizations of import of Non Psychoactive Cannabis or Hemp Derivatives manufactured abroad by the National Agrarian Authority, will be granted on the surpluses of national production.

**Article 18.- Regarding the export of seeds, cuttings and seedlings:** For the export of Non Psychoactive Cannabis or Certified Hemp Seeds, Cuttings and Seedlings or certified Hemp Seeds for Industrial Use, for production, processing and industrialization and commercialization purposes, it shall comply with the requirements established in the LOASFAS, Organic Law of Agricultural Health (hereinafter LOSA by its Spanish acronym) and its respective regulations.

**Article 19.- Export of Biomass or Non-Psychoactive Cannabis or Hemp Flower, or Hemp Biomass for Industrial Use:** The Licensees that have the License for the Cultivation of Non-Psychoactive Cannabis or Hemp, or the License for the Cultivation of Hemp for Industrial Use, or the License for the Acquisition of Derivatives and/or Biomass or Flower of Non-Psychoactive Cannabis or Hemp, or Biomass of Hemp for Industrial Use, for Export, they may export Biomass or Non Psychoactive Cannabis or Hemp flower, or Hemp Biomass for Industrial Use, or in grain, prior notification to the National Agrarian Authority and complying with the requirements established in the LOSA and its regulations.

**Article 20. - Export of Non-Psychoactive Cannabis or Hemp Derivatives:** In the case of export of Non-Psychoactive Cannabis or Hemp Derivatives, those licensees that have the License for the Acquisition of Derivatives and/or Biomass or Flower of Non-Psychoactive Cannabis or Hemp, or of Biomass of Hemp for Industrial Use, for Export,

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and the License for the Processing of Non-Psychoactive Cannabis or Hemp and Production of Non-Psychoactive Cannabis or Hemp Derivatives, may export.

**Article 21.- Record of Transactions:** The Licensee will maintain adequate magnetic records, for a period of ten years, which will be available for inspection by any authorized representative of the National Agrarian Authority; of all transactions referring to the commercialization of Non-Psychoactive Cannabis or Hemp Derivatives, or Non-Psychoactive Cannabis or Hemp Biomass and/or Flower or Hemp Derivatives for Industrial Use for human consumption.

Each transaction made by Licensee must be recorded separately on an invoice containing the requirements of applicable regulations.

### CHAPTER VI

#### LICENSES AND REQUIREMENTS

**Article 22.- Types of Licenses:** The National Agrarian Authority shall issue the following Licenses:

1. License to Import and Commercialize Non-Psychoactive Cannabis or Hemp Seeds, or Non-Psychoactive Cannabis or Hemp Cuttings, or Hemp Seeds for Industrial Use (LICENSE 1)
2. License for the Plating and Production of Non-Psychoactive Cannabis or Hemp Seeds, or Non-Psychoactive Cannabis or Hemp Cuttings, or Hemp Seeds for Industrial Use (LICENSE 2)
3. License for the Cultivation of Non-Psychoactive Cannabis or Hemp (LICENSE 3)
4. License for the Cultivation of Hemp for Industrial Use. (LICENSE 4)
5. License for the Processing of Non-Psychoactive Cannabis or Hemp and Production of Non-Psychoactive Cannabis or Hemp Derivatives (LICENSE 5)
6. License for Plant Breeding and/or Germplasm Banks and Research (LICENSE 6)
7. License for the Acquisition of Derivatives and/or Biomass or Flower of Non-Psychoactive Cannabis or Hemp, or Hemp Biomass for Industrial Use, for Export (LICENSE 7)

Each one of the above-mentioned Licenses will entail the possibility of carrying out activities proper to the business line and others related to the activities that are authorized, such as storage, transport, commercialization and export, previous the fulfillment of the specific requirements for each one of the activities.

The Licensees that have the License 3, will not be able to alienate, sell, commercialize or distribute Derivatives of Non Psychoactive Cannabis or Hemp for the consumption or human or animal use, unless they have the License 5 granted by the National Agrarian Authority.

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The Licensees that have the License 3, will not need to obtain the Licenses 1 and/or 2, to develop the activities anticipated in these last two Licenses, but they will have to fulfill the requirements anticipated in this Regulation for these Licenses.

The Licensees that have the License 4, will not need to obtain the Licenses 1 and/or 2, to develop the activities anticipated in this last two Licenses, but they will have to fulfill the requirements anticipated in this Regulation for these Licenses, having to clarify that these Licensees will only be able to import and to produce Hemp seeds for Industrial Use.

The Licensees that have the License 3, will be able to acquire between them, Biomass and/or flower of Not Psychoactive Cannabis or Hemp, and will be able to export those products without necessity to obtain the License 7, as long as the Licensee is operative and up-to-date in the plan of agricultural production presented.

License 7 authorizes Licensees to acquire, import and commercialize derivatives and/or Biomass or flower of Non-Psychoactive Cannabis or Hemp, or Biomass of Hemp for Industrial Use and also Derivatives of Non-Psychoactive Cannabis or Hemp, for export.

The Licensees that have the License 5, will only be able to acquire Biomass of those Licensees that have the License 3.

License 3 authorizes Licensees to sell, commercialize, export and distribute Biomass to Licensees holding Licenses 5 and/or 7.

License 4 authorizes Licensees to sell, commercialize, export and distribute Biomass to Licensees holding the License 7.

Once the National Agrarian Authority issues a License 3, which sowing is in open air, it will not grant the License 4, when its purpose is the production of grain, 2 km away from the already authorized Cultivation Area, measured from any point of the perimeter of the previous Licensee, to avoid the propagation of pollen that affects the quality of already authorized plantations.

Licenses are non-transferable, and will specify the following:

- a.** Name, Taxpayer Registry (RUC by its Spanish acronym), Business name and address of the Licensee;
- b.** Activities allowed by the License;
- c.** The land, buildings and facilities, which may be used or exploited for the activities authorized to the Licensee;
- d.** Date of issue and validity;
- e.** A unique license number issued by the National Agricultural Authority; and
- f.** Any other information that the National Agrarian Authority considers necessary.

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The National Agrarian Authority will have the faculty to limit the number of licenses, to regulate the supply and the demand, as well as to limit in each License, the amount of Non Psychoactive Cannabis or Hemp for Industrial Use that is allowed to be cultivated.

**Article 23.- General Requirements for obtaining Licenses:** For all types of Licenses, the Applicant shall submit to the National Agrarian Authority the following general requirements, which shall be accompanied by the specific requirements for each License as indicated in these Regulations:

- a. Form for Licenses of Non-Psychoactive Cannabis or Hemp, or Hemp for Industrial Use (ANNEX 1).
- b. Simple copy of the Taxpayer Registry (RUC), which must include the activity or activities to be carried out by the Applicant, information that will be verified on the website of the competent institution.
- c. A simple copy of the statutes of the legal entity, public entity, cooperative, association or commune, legally constituted, whose object includes the activities to be developed by the Applicant.
- d. Certified copy of appointments of legal representatives.
- e. Affidavit issued by the legal representative of the applicant, granted by a notary public, with the detail of the activities they will perform for this purpose, which must be related to the application.
- f. Certificate of criminal record of the legal representative of the Applicant, its directors and partners, shareholders or members who have a participation greater than 6% of the company's capital, through which it will be verified that they have not been declared criminally responsible by means of a final conviction, for crimes of drug trafficking, money laundering, corruption and related crimes. In case the shareholders or partners are legal entities, the certificate of the last natural persons in the chain of shareholders or partners of the legal entities must be presented, except if those legal entities are registered in any Stock Exchange, or if it is a case of an investment fund. In the case of foreign companies, they must submit the equivalent document issued by the competent authority of the country of origin, duly legalized.
- g. A document detailing the organizational structure of the applicant and its members. In case the shareholders, partners or members are legal entities, the last natural persons in the chain of shareholders or partners of the legal entities must be disclosed, except if those legal entities are registered in a Stock Exchange or an investment fund.
- h. Form of licitness and destination of funds (ANNEX 2).
- i. Payment receipt of the fee according to the type of license to which it applies, as detailed in the corresponding tariff.

**Article 24.- Specific requirements for each License:** In addition to the general requirements detailed in article 24 of these Regulations, Applicants shall attach the specific requirements, depending on the type of License to which they are applying, as established in these Regulations.

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**Article 25. - License for the Importation and Commercialization of Non-Psychoactive Cannabis or Hemp Seeds, or Non-Psychoactive Cannabis or Hemp Cuttings, or Hemp Seeds for Industrial Use - LICENSE 1:** Without prejudice the requirements set forth in LOASFAS, the LOSA and their respective regulations, for the import of plant material, the Applicant interested in importing Non-Psychoactive Cannabis or Hemp Seeds, or Non-Psychoactive Cannabis or Hemp Cuttings, or Hemp Seeds for Industrial Use, shall submit:

- a. Affidavit issued by the Applicant's legal representative or General Attorney, granted by a notary public, stating that the THC content of genetic material to be imported is less than 1% in dry weight.
- b. Certificate issued by the agricultural authority of the country of origin of the seeds, duly apostilled or legalized, in which the following is detailed:
  1. The quality and variety of the seeds to be provided;
  2. That they are suitable seeds to cultivate Not Psychoactive Cannabis or Hemp, or Hemp for Industrial Use;
  3. That its content of THC is lower than 1% in dry weight;
  4. Phytosanitary certificate of the seeds.

If the agricultural authority of the country of origin of the seeds does not certify one or more of the above requirements, the Applicant must attach an affidavit from the breeder of the seeds containing all the requirements set forth in this letter b, which must be notarized and apostilled or legalized.

Documents issued in a foreign language must be duly translated into Spanish.

The Applicant must request the respective authorization, for each import, which will be the authorizer to start the process of the Phytosanitary Import Permit – PFI (by its Spanish acronym) with AGROCALITY.

Applicant shall indicate the location of the Storage Areas where Non-Psychoactive Cannabis or Hemp Seeds, or Hemp Seeds for Industrial Use, or Non-Psychoactive Cannabis or Hemp Cuttings will be collected.

**Article 26.- License for the Plating and Production of Non-Psychoactive Cannabis or Hemp Seeds, or Non-Psychoactive Cannabis or Hemp Cuttings, or Hemp Seeds for Industrial Use — LICENSE 2:** Without prejudice to the requirements established in LOASFAS, the LOSA and its regulations, the Applicant interested in sowing and producing Non-Psychoactive Cannabis or Hemp Seeds, or Non-Psychoactive Cannabis or Hemp Cuttings, or Hemp Seeds for Industrial Use, must submit a certificate issued by the legal representative or General Attorney of the Applicant, detailing the following:

- a) The quality and variety of the seeds to be sown;

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- b) That they are suitable seeds to cultivate Cannabis Not Psychoactive or Hemp or Hemp for Industrial Use;
- c) That its THC content is less than 1% in dry weight;

The planting and production of Non-Psychoactive Cannabis or Hemp Seeds, or Non-Psychoactive Cannabis or Hemp Cuttings, or Hemp Seeds for Industrial Use, should be done under a greenhouse or other closed structure that prevents the escape of Pollen.

The Applicant must indicate the location of the Cultivation Areas where the Non-Psychoactive Cannabis or Hemp Seeds, or Hemp Seeds for Industrial Use, or Non-Psychoactive Cannabis or Hemp Cuttings will be planted. A plan of the area of Production of Seeds or Cuttings must be attached, duly demarcated, in which the Cultivation Area must be indicated, which will be accompanied by the boundary (polygon) of the property or space destined for the cultivation, which must be delivered to the National Agrarian Authority in a digital file, in shapefile format, with the following cartographic parameters: UTM (Universal Transverse Mercator) flat coordinates, WGS84 Reference System, Zone 17 South.

**Article 27.- License for the Cultivation of Non-Psychoactive Cannabis or Hemp - LICENSE 3:** In order to obtain the License for the Cultivation of Non-Psychoactive Cannabis or Hemp, the Applicant must present the following requirements to the National Agrarian Authority:

- a. Plan of the Cultivation Area duly demarcated in which the number of hectares for cultivation must be indicated, which will be accompanied by the boundary (polygon) of the property or space destined for cultivation, which must be delivered to the National Agrarian Authority in a digital file, in shapefile format, with the following cartographic parameters: UTM (Universal Transverse Mercator) flat coordinates, WGS84 Reference System, Zone 17 South.
- b. The Cultivation Area cannot be part of protected areas or primary forests or be located in border or national security zones.
- c. Property deed or rental contract duly legalized, or any other document that accredits the use and enjoyment of the property. In case of rented land, the Applicant must present the contract stating that the land will be used for the Cultivation of Non-Psychoactive Cannabis or Hemp.
- d. Agricultural Production Plan describing the responsibilities to be fulfilled by the Applicant during the cultivation stage, which should detail the following:
  - 1. The number of hectares destined to produce and the detailed density in plants/hectare.
  - 2. Description of the project and the purpose of the cultivation.
  - 3. Description of the estimated quantities to be harvested.
  - 4. The origin and source of the seeds or vegetative material to be used in the project.
  - 5. Traceability registration plan for Non-Psychoactive Cannabis Seeds or Hemp, or Non-Psychoactive Cannabis or Hemp Seedlings, or Non-Psychoactive



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Cannabis or Hemp Plants, from planting to production, with the aim of identifying the final product.

6. Plan for the elimination of male plants to avoid the propagation of Pollen that affects the quality of third party plantations.
7. Plan of Good Agricultural Practices applicable to the sowing of Non-Psychoactive Cannabis or Hemp Seeds, or Non-Psychoactive Cannabis or Hemp Seedlings, or Non-Psychoactive Cannabis or Hemp Plants, to be implemented within twelve months from the date of granting of the respective License.

This License allows the sale of Biomass and/or Non-Psychoactive Cannabis or Hemp Flower to other Licensees with the respective authorization.

**Article 28.- License for the Cultivation of Hemp for Industrial Use - LICENSE 4:** In order to obtain the License for the Cultivation of Hemp for Industrial Use, the Applicant shall submit to the National Agrarian Authority, the following requirements:

- a. Plan of the Cultivation Area duly demarcated in which the number of hectares for cultivation must be indicated, which will be accompanied by the boundary (polygon) of the property or space destined for cultivation, which must be submitted to the National Agrarian Authority in a digital file, in shapefile format, with the following cartographic parameters: UTM (Universal Transverse Mercator) flat coordinates, WGS84 Reference System, Zone 17 South.
- b. The Cultivation Area cannot be part of protected areas or primary forests or be located in border or national security zones.
- c. Property deed or rental contract duly legalized, or any other document that accredits the use and enjoyment of the property. In case of rented lands, the Applicant will have to present the contract in which it is stated that the land is going to be destined to the culture of Hemp for industrial use.
- d. Agricultural Production Plan describing the responsibilities to be fulfilled by the Applicant in the stage of cultivation of Hemp for Industrial Use, which should detail the following:
  1. The number of hectares destined to produce and density of sowing per plot or lot detailed in kilograms/hectare.
  2. Description of the project and the purpose of the cultivation.
  3. Description of the estimated quantities to be harvested.
  4. The origin and source of the seeds or vegetative material to be used in the project.
  5. Plan of Good Agricultural Practices applicable to the sowing of Hemp for Industrial Use, which must be implemented within a period of twelve months from the date of concession of the License.
  6. Plan of traceability of lots of the culture of Hemp for Industrial Use, from its sowing to its commercialization or final disposition.

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This License authorizes the production of Hemp for Industrial Use and its commercialization as biomass.

**Article 29.- License for the Processing of Non-Psychoactive Cannabis or Hemp and Production of Non-Psychoactive Cannabis or Hemp Derivatives - LICENSE 5:** To obtain the License for the Processing of Non-Psychoactive Cannabis or Hemp and Production of Non-Psychoactive Cannabis or Hemp Derivatives, the Applicant must submit to the National Agrarian Authority, in the offices authorized by it, the respective application in the form established by said Authority, with the following requirements:

- a. Description of the type of facilities that will be used for the project.
- b. The location of the establishment where the processing activities will take place, which must be properly fenced. For this purpose, the Applicant shall deliver the plan of the facilities and the duly demarcated place, with areas and geo-reference.
- c. Property deed or rental contract duly legalized or any other document that accredits the use and enjoyment of the property. In case of rented land, the Applicant must present the corresponding lease contract in which it is stated that the land will be used for the processing of Non-Psychoactive Cannabis or Hemp.
- d. Good Manufacturing Practices Plan applicable to the processing of Non-Psychoactive Cannabis or Hemp, which must be implemented within twelve months from the date of granting of the respective License. The implementation of the Good Manufacturing Practices Plan does not imply obtaining a Certificate of Good Manufacturing Practices.
- e. Plan of the Facilities for the Production of Derivatives.
- f. Non-Psychoactive Cannabis or Hemp Processing Plan, describing the Applicant's responsibilities at each stage of processing, which should include at least the following:
  1. Description of the type of facility you will use for the project, organization chart and number of employees.
  2. Description of equipment, process controls, testing capabilities and process safety.
  3. Description of the quantities to be processed and for what purpose or market it will be used.
  4. The origin and source of the raw material to be used in the processing.
  5. Batch traceability registration plan of the derivatives, for which the interpretation of the batch code must be included.
  6. Flow chart of the transformation process to be implemented at the production site, including procedures for raw material reception, quality control and batch release; and,
  7. SOP for the control and treatment of contaminated, expired, deteriorated or returned products, which should include the process of destruction of these products.

**Article 30.- Plant Breeding License and/or Germplasm Banks and Research - LICENSE 6:** Without detriment to the requirements established in the Organic Law on

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Agrobiodiversity of Seeds and Promotion of Sustainable Agriculture (LOASFAS) and its regulations, those interested in acquiring a license for plant breeding purposes and/or germplasm banks and research for food and agriculture shall submit the following requirements:

- a. Plan of the Cultivation Area duly demarcated in which the number of hectares for cultivation must be indicated, which will be accompanied by the boundary (polygon) of the property or space destined for cultivation, which must be delivered to the National Agrarian Authority in a digital file, in shapefile format, with the following cartographic parameters: UTM (Universal Transverse Mercator) flat coordinates, WGS84 Reference System, Zone 17 South. Registration according to the LOASFAS and its Regulations.
- b. List of Cultivars of Non-Psychoactive Cannabis Seeds or Hemp, or Hemp for Industrial Use preserved and/or to be preserved.

The research related to Non Psychoactive Cannabis or Hemp, or of Hemp for Industrial Use, its seeds, plants and derived products, will have to be carried out by a university or a legally constituted legal person, in whose social object the breeding is found.

In order to assure the destination of the product obtained from the research (biomass, flower, fibers, grains, or other parts of the plant), the document that accredits the legal link must be presented to the National Agrarian Authority exclusively for research purposes, expressing the quantity of product to be provided, which must be related to what is established in the research project.

The activities covered by this License shall be carried out under greenhouses or closed structures that prevent the release of pollen.

**Article 31. - License for the Acquisition of Derivatives and/or Biomass or Non Psychoactive Cannabis or Hemp Flower, or Hemp Biomass for Industrial Use, for Export - LICENSE 7:** To obtain the License for the acquisition of Derivatives and/or Biomass or flower of Non Psychoactive Cannabis or Hemp, or Biomass of Hemp for Industrial Use, for Export, the Applicant must present to the National Agrarian Authority, in the dependencies authorized by it, the respective application in the form established by such Authority, with the following requirements:

- a. Storage and Transportation Plan.
- b. List of countries to which it will be exported;
- c. Batch traceability plan of the derivatives and/or the biomass or flower.

**Article 32.- Procedure for obtaining licenses:** Depending on the type of License, the Applicants shall present all the requirements detailed in these Regulations to the offices that the National Agrarian Authority establishes for such purpose, as indicated below:

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- a. A folder with all the requirements must be submitted, which must include a copy of the file on magnetic media duly labeled.
- b. Prior to the submission of the documents at the counter, the file will be subject to prior review in order to verify that all the documents and/or requirements have been included, a review that will not deal with the substance of the documents submitted. A checklist will be attached to this review, detailing whether all the documents or requirements have been included, and if not, the file will be rejected until the missing documents/requirements are completed.
- c. In those cases where the file is complete, as indicated in the checklist, it will be received.
- d. The Undersecretary for Agricultural Production shall analyze the documents submitted within 30 days of the date of receipt of the application. If positive, the license will be issued.
- e. In case the application is observed, the Applicant must correct the inconsistencies that have been identified, within 30 days from the date the National Agrarian Authority notifies it with the observations. If the inconsistencies are not corrected within the specified period, the application will be filed.
- f. Once the observations have been corrected, the National Agrarian Authority must issue a pronouncement within 30 days from the submission of the documentation. If it is positive, it shall proceed with the issuance of the License, within a term of 7 days.
- g. In case the inconsistencies have not been corrected and consequently the pronouncement is negative, the Applicant must correct the inconsistencies within 10 days from the date the National Agrarian Authority notifies it. In case the inconsistencies are not corrected within the term specified, the procedure will be filed.
- h. Once the inconsistencies have been corrected, the National Agrarian Authority must make a decision within 15 days from the date of submission of the documentation. If it is positive, it will proceed with the issuance of the License. In case of being negative, the application will be filed.
- i. In those cases in which the Applicant does not submit the documentation in the detailed terms, the application will be filed, and the process will be initiated again.
- j. The filing of the processes implies that the Applicant will have to start the whole process again and will have to pay a new fee.
- k. The National Agricultural Authority may verify the authenticity of the submitted documentation.

**Article 33.- License Fees:** The National Agrarian Authority shall establish, by means of a Ministerial Agreement, the fees corresponding to the issuance of each type of License. The Applicant shall submit, together with the requirements determined for each type of License, the receipt for the payment of the corresponding fee.

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In case the process is declared closed because the inconsistencies notified by the National Agrarian Authority have not been corrected, the value paid for the license or renewal fee will not be returned to the Applicant or the Licensee.

Universities that would like to obtain a Plant Breeding License and/or Germplasm Banks and Research are not required to pay the fee applicable to this type of license.

The Licensee shall pay the annual maintenance fee set by the National Agrarian Authority, during all the years its License is in force. This annual fee shall be paid within 30 days as from the date of issuance of the granted License. Failure to pay the annual maintenance fee will result in the temporary suspension of the License and in case of failure to comply with the payment for a period longer than 3 months, the procedure for its revocation will be initiated.

**Article 34.- Validity of Licenses:** The Licenses that are issued by virtue of this Regulation will be valid for 10 years, starting from the date of their granting and may be renewed.

During the term of the License, the Licensees must notify the National Agrarian Authority of all modifications to the activity, operation and shareholding structure of the Licensee, as established in these Regulations, which served as the basis for the issuance of the favorable feasibility report and the respective License or renewal. The Licensee is obliged to keep its file updated, for which purpose it must notify the National Agrarian Authority of any change or update made with respect to the requirements detailed in these Regulations for each type of License.

**Article 35.- Renewal of Licenses:** The Licensees shall request the renewal of their Licenses, ninety (90) days prior to the expiration date of said Licenses and by submitting the corresponding renewal request.

The automatic renewal is the procedure by means of which, the License is renewed, once its period of validity has concluded, as long as the activity and the information related to the Licensee and its operation, continues being the same one that was presented in the original process of obtaining the License or in case of having existed changes, these had been notified opportunely according to the indicated in these Regulations.

To proceed with the automatic renewal, the Licensee must submit the Non-Psychoactive Cannabis or Hemp or Industrial Hemp License Form (ANNEX 1) and the receipt of payment of the corresponding fee, according to the current tariff.

If the activity, the operation or the information of the Licensee has suffered modifications or the documentation that rests in the file of the License has not been updated opportunely, the modification or update cannot be presented together or in parallel with the request of renewal.

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In case it is verified that the activity, the operation or the information of the shareholding structure of the Licensee has suffered modifications or that the documentation that rests on the file of the License has not been updated opportunely, the Licensee will not be able to use the process of automatic renewal and will have to present the request for obtaining a new License using the process of obtaining the License for the first time, attaching all the requirements detailed in these Regulations for each type of License.

Both those Licensees who use the automatic renewal process and those who must use the process of obtaining a License for the first time, will maintain the License number that was granted when the License was obtained for the first time.

**Article 36.- Modification of the Licenses:** Any modification to the information and documentation that served for the granting of the respective License, as well as any change in the activity or the Licensee, shall be notified to the National Agrarian Authority within a term of 30 days as from the effective date of the modification. The notification shall be made through the Form for Licenses of Non-Psychoactive Cannabis or Hemp, or Hemp for Industrial Use, annexed to these regulations, attaching the support documents, through which the modification is evidenced.

In case of inconsistencies in the information provided in the form or in the compliance with the applicable requirements according to the type of License, the National Agrarian Authority will issue a report with the observations it finds. The Licensee must correct the inconsistencies detected within 15 days from the date of notification. The modification or update of the License shall not take effect until the inconsistencies notified by the National Agrarian Authority have been remedied.

**Article 37.- New licenses:** A new license shall be obtained in the following cases:

- a. Change of place of cultivation or production;
- b. Change of crop type

In the event of any other modification to the aforementioned, the National Agrarian Authority must be notified in accordance with the procedure established in Article 37 of these Regulations. The license number 5 and 7 are excluded from this article.

**Article 38.- Suspension, Revocation or Refusal to Renew Licenses:** The National Agrarian Authority may suspend or revoke a License or deny its renewal, prior notification to the Licensee in case the National Agrarian Authority verifies the following:

- a. Any statement contained in an application by an Applicant or Licensee is false.
- b. Data or information was omitted in order to avoid the licensing or renewal process being rejected.

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- c. If it is proven that the money and other resources used in the project come from illegal sources, such as money laundering, drug trafficking, corruption or related crimes established in the Comprehensive Criminal Code.
- d. If it is verified that the legal representative of the Licensee, its General Attorney, its directors or the partners or shareholders that have a participation greater than 6% in the capital stock of the Licensee, have been convicted by means of a final judgment, for crimes of drug trafficking, money laundering, corruption and related.
- e. Any transfer of shares exceeding 6% of the capital stock of the Licensee has been made without the prior authorization of the National Agrarian Authority, which must verify the suitability of the eventual transferee and the legality of the funds. In this case, the Licensee must present the personal criminal record certificate of the new shareholders that have a participation greater than 6% of the capital stock.
- g. The Licensee has not submitted or has unjustifiably refused to submit the information related to the compliance of this Regulation, formally and justifiably required by the National Agrarian Authority, within the term established by the National Agrarian Authority in the information request; or
- h. If the Licensee or its legal representatives or technical representative have not complied with any of the provisions of these Regulations.

If any of the irregularities detailed above are found in a license that has already been granted, the National Agrarian Authority may suspend, revoke or deny the renewal of the license, for which it must issue a reasoned report.

**Article 39.- Procedure in case of Suspension, Revocation, or Refusal to Renew Licenses:** The National Agrarian Authority or its delegate shall notify the Licensee with the resolution of the suspension, revocation, or refusal to renew the License; and, the Licensee shall be given a term of ten (10) days, renewable for an equal period at the request of a party, to file the respective discharges.

If the National Agrarian Authority considers that the fault committed by the Licensee is very serious, it may order the immobilization of the inventories and assets and shall order the temporary closure, through the placement of security seals.

In the case of imports arrived to the country, which are in primary zones and belong to the Licensee, the National Agrarian Authority will order to notify the National Customs Authority with the impediment of the nationalization of the products, until the final resolution is issued.

Once the discharges have been presented and the evidentiary proceedings have been carried out, within five days, the National Agrarian Authority will pronounce itself in sole and definitive instance. If the existence of one or more of the faults detailed in the preceding article is established in said report, the measure shall be ratified.

If the security seals have been altered or it is proven that by any means the derivatives that were immobilized have been used, these circumstances will be recorded in a technical report that will be sent to the National Agrarian Authority.

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### CHAPTER VII ABOUT THE ADMINISTRATIVE CONTROL REGIME

**Article 40.- About Control:** The Undersecretary of Agricultural Production will carry out and strengthen the control in all the national territory, for the import, sowing, cultivation, harvest, production, processing, commercialization and export of Non Psychoactive Cannabis or Hemp, or of Hemp for Industrial Use.

**Article 41.- Transfer of shares or holdings:** The transfer of shares, or holdings, in a percentage equal to or greater than 6% of the capital stock, must be previously authorized by the National Agrarian Authority, in order to verify the suitability of the transferees.

Regardless of the paragraph above, the transfer of shares, participations or change of control of the Licensee, in a percentage higher than 50% of the capital stock, may only be carried out after the project referred to in the License granted is in operation and at least one cycle of 0.5 hectares or more has been executed.

**Article 42.- Request and Access to Information:** The National Agrarian Authority may require from the Licensees or Applicants of a License, the following:

- a. General information about the Licensee or the Applicant.
- b. Information on the ownership and investments of the Licensees or Applicants, including corporate structure.
- c. Criminal record certificates of the legal representatives or proxies of the Applicants or Licensees, or of the partners or shareholders or members having a participation greater than 6%.
- d. Information about the establishments or cultivation areas that will be licensed.
- e. Company financial statements; or
- f. Any other information established in the regulations issued by the National Agrarian Authority.

The National Agrarian Authority will have the faculty to obtain data and research about, among other things, genetics, methods for cultivation, production and processing of Non Psychoactive Cannabis or Hemp, or Hemp for Industrial Use and the products derived from it.

The National Agrarian Authority may request, receive, and review information about criminal records regarding any Applicant or Licensee to engage in any of the activities related to Non-Psychoactive Cannabis or Hemp, or Hemp for Industrial Use.

The information provided by Applicants and Licensees is presumed to be true, correct and binding on them.



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**Article 43.- Access to areas and establishments:** The National Agrarian Authority shall have full access to all Cultivation Areas, Post-Harvest Areas and Storage Areas, as well as to all premises, buildings, factories, vehicles, boats, airplanes, ships, containers, packages, barrels, boxes and/or cans with the purpose of enforcing the terms of these Regulations. In those places, the National Agrarian Authority will be able to examine the Non Psychoactive Cannabis or Hemp, or Hemp for Industrial Use and the derived products and will be able to open any package and/or container that is presumed to contain Non Psychoactive Cannabis or Hemp, or Hemp for Industrial Use or derived products, with the purpose of determining if they comply with the applicable laws and regulations.

The Licensees will have the obligation to provide all the necessary facilities and allow access to the servers or delegates that the National Agrarian Authority authorizes for this purpose.

Non-compliance with the precepts established in this article shall be cause enough for the imposition of the sanctions provided for in these Regulations, after the corresponding administrative procedure.

**Article 44. - Registration Orders:** In case a Licensee has refused to allow the inspection of any Non-Psychoactive Cannabis or Hemp, or Hemp for Industrial Use or its derivatives, to take samples of these; to allow the access to any premises or place where the activities object of the License are carried out; and/or impeded or obstructed in any way the access to the official/inspector of the National Agrarian Authority; and, if this Authority has reasonable grounds to presume that such Licensee has in its possession or under its control any Non-Psychoactive Cannabis or Hemp, or Hemp for Industrial Use and/or derived products that are in violation of the provisions of these Regulations, the National Agrarian Authority may request the competent judge to issue an order for:

- a. Search any place of business, factory, collection center, building, premises or farm where activities authorized in the License have been or are being conducted, as well as any vehicle, boat, vessel, container, package, barrel, box, pipe or can containing or believed to contain Non-Psychoactive Cannabis or Hemp, or Hemp for Industrial Use in the possession or under the control of any person who refuses to allow access for inspection or sampling; and,
- b. Inspect or sample any Non-Psychoactive Cannabis or Hemp, or Hemp for Industrial Use or derivative found during the execution of the registration mentioned in the previous paragraph.

**Article 45.- Inspections:** In order to guarantee the observance and fulfillment of the requirements and other provisions established in these Regulations, the National Agrarian Authority shall carry out inspections to the property authorized in the License, to verify the Cultivation Area, the quantity of plants planted, the THC levels and other requirements established in these Regulations.

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Inspections must be authorized by the Undersecretary of Agricultural Production and shall be carried out randomly without prior notification to the Licensees. The District Director or designated inspectors shall be responsible for carrying out the inspections provided for in this article.

The inspections may be conducted by expert technicians-auditors in this field, previously qualified and registered with the National Agrarian Authority.

The District Director of the National Agrarian Authority or the inspectors designated by this authority, may enter any establishment or Cultivation Area, to inspect or verify compliance of the requirements established in these Regulations, for which they must present the identification credentials and the authorization issued by the Undersecretary of Agricultural Production.

Each inspection shall be recorded in minutes signed by the District Director of the National Agrarian Authority or the designated inspector who conducts the visit. The minutes shall include any new information found and irregularities identified during the inspection, if applicable, and the period of time the Licensee shall have to correct them.

The Licensees shall be compelled to provide all the facilities for the National Agrarian Authority to carry out the pertinent inspections, and in the event that access is denied, they will face the sanctions provided for in these Regulations.

**Article 46.- Transportation Requirements:** Any person that transports biomass and/or Non Psychoactive Cannabis flower or Hemp must:

- a. Have a referral guide (shipping documents) in their possession.
- b. Notice the National Police to request custody of the shipment.
- c. Comply with the requirements established by the Agricultural Health Law and its regulations regarding the transport of plants, plant products and regulated articles.
- d. Must have satellite tracking service.

**Article 47. - Traceability:** The traceability process will be controlled by a web and mobile technology platform based on "open source", which allows the management of the processes of internal and external users involved in the traceability, planning, control and monitoring of Non Psychoactive Cannabis or Hemp or its derivatives, in a safe way, with integration of tools for the management of geo-referenced data, implementing technological services oriented to the simplification of procedures, for which, each of the phases will be determined for its independent administration with high security, and the fulfillment of adaptable rules of interconnection and validation that communicate to the technological platform of traceability with the computer systems of entities involved in the process.

The modules must be connected to each other with homogeneous rules and protocols that allow the information to be stored and validated through the same network, for which the

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information can be consulted by all registered users, with the use of specific profiles by means of certificates endorsed through intelligent contracts. In the case of Non Psychoactive Cannabis or Hemp, the database will be decentralized and cryptographically protected, with a copy of all stored information, which will allow having a business intelligence tool for the analysis and interpretation of data from different sources, entities and computer systems involved in the production chain, planning, control and monitoring for timely and efficient decision making.

**Article 48.- Abandoned operations:** It is the responsibility of the Licensee to eliminate all the vegetal material of Non Psychoactive Cannabis or Hemp, or Hemp for Industrial Use, before vacating the property where the cultivation is developed and that is registered in the License or in case of discontinuing the cultivation of Non Psychoactive Cannabis or Hemp, or Hemp for Industrial Use.

### CAPÍTULO VIII IRREGULARITIES, INFRACTIONS AND SANCTIONS

**Article 49.- Irregularities:** In case any of the following irregularities are identified within the inspection process; and, as long as they are not fully corrected within the term established by the National Agrarian Authority, the Licensee will be subject to an administrative process in accordance with the provisions of the Organic Administrative Code – COA (for its Spanish acronym) and sanctioned as detailed in these Regulations:

- a. If it is found that there are new unauthorized plantings, or an area larger than that authorized.
- b. If it is identified that the purpose of the cultivation is different from the one stated in the License.
- c. If it is determined that modifications have been made to the documentation or information contained in the file of the License and that they have not been duly notified in accordance with the provisions of these Regulations.

**Article 50.- Penalties:** Carrying out any activity with Non Psychoactive Cannabis or Hemp, or Hemp for Industrial Use or its derivatives without having been previously licensed by the National Agrarian Authority, or the commission of the infractions described in these Regulations, shall give rise to the imposition of the sanctions herein foreseen prior to the corresponding administrative sanctioning procedure, without prejudice to the corresponding civil and criminal actions.

**Article 51.- Types of sanctions:** The infractions determined in these Regulations shall be sanctioned by the National Agrarian Authority, according to the case, with:

- a. Fine.
- b. Temporary suspension of the License for up to 30 working days or until the breach is remedied.
- c. Definitive revocation of the license.

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- d. Confiscation, disposal of vegetative material, its derivatives or other products subject to these Regulations.
- e. Closure, temporary or definitive of the establishment according to the case.

**Article 52: Minor infractions and sanctions:** The Licensee that commits any of the following infractions shall be sanctioned with a fine of five (5) to ten (10) unified basic salaries and temporary suspension of the License for a term of 30 days:

- a. Not allow investigation, inspection or sampling, authorized by the National Agrarian Authority, or hinder the work of the inspectors authorized by the National Agrarian Authority in compliance with their functions and activities of prevention, inspection and control set forth in these Regulations;
- b. Transport or mobilization of biomass and/or flowers or other regulated articles, without complying with the provisions detailed in these Regulations.
- c. Failure to timely notify the National Agrarian Authority of changes in the License that should be informed in accordance with the provisions of these Regulations.
- d. Failure to immediately notify the National Agrarian Authority of the outbreak of a disease or pest under official control in the scope of its agroproductive activities.
- e. Failure to comply with the transportation requirements provided for in these Regulations.

**Article 53: Serious Infractions and Sanctions:** The Licensee who commits any of the following infractions shall be sanctioned with a fine of eleven (11) to twenty-five (25) unified basic salaries and temporary suspension of the License for a term of 60 days:

- a. Failure to comply, as of the date of notification and within the established period, with the technical, preventive or enforcement measures issued by the National Agrarian Authority.
- b. Export and import plants and plant products or other regulated articles without the respective authorization of the National Agrarian Authority, obtained prior to shipment.
- c. Failure to comply with the resolution of confiscation, immobilization of plants and regulated products, issued by the National Agrarian Authority.

**Article 54: Very serious infractions and sanctions:** The Licensee that commits any of the following infractions shall be sanctioned with a fine of fifty (50) unified basic salaries and the definitive revocation of the License:

- a. Planting, producing, commercializing, transporting or distributing, Non-Psychoactive Cannabis or Hemp, or Hemp for Industrial Use or its derivatives, without the respective License.
- b. Planting Non-Psychoactive Cannabis or Hemp, or Hemp for Industrial Use in areas other than those authorized in the respective License.
- c. Adulterating, modifying, supplanting certificates, licenses, reports or other official documents issued by the National Agrarian Authority.

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- d. Illegal use or transfer of the Licenses, without prejudice to any criminal actions.
- e. Produce or commercialize adulterated products that do not comply with the parameters established in this Regulation.
- f. Adulterating, modifying, supplanting certificates, licenses, reports or other official documents issued by the National Agrarian Authority.
- g. Failure to comply with the obligations provided for in Article 56 of these Regulations.

The legal representatives or General Proxies or partners or shareholders of the Licensees that have been sanctioned for any of the causes established in this article, may not obtain any of the Licenses provided for in these Regulations, for a period of 5 years starting from the date of the sanction imposed by the National Agrarian Authority.

**Article 55: Additional responsibilities:** In case of committing the infractions detailed in article 50, in addition to the penalties applied, the offender shall pay 100% of the costs, and other expenses demanded by the application of the phytosanitary measures, the incineration or destruction of the material or derivatives that the National Agrarian Authority may order.

The application of sanctions to the infractions described above shall not stop the National Agrarian Authority from ordering, as a complementary measure to the very serious infractions, the seizure, destruction and elimination of the crops involved or the revocation of the licenses and closure in accordance with these Regulations.

In case the infraction has indications of criminal responsibility, the file will be sent to the competent authority.

**Article 56. - Deadline for Remediation:** If the National Agrarian Authority determines, either ex officio or by private denunciation, that the Licensee authorized to carry out any of the activities related to Non-Psychoactive Cannabis or Hemp, or Hemp for Industrial Use and object of these Regulations, has failed to comply with any provision and/or regulation promulgated in accordance with these Regulations, the Licensee in question shall be required to comply with a corrective action plan established by the National Agrarian Authority to correct the violation up to a reasonable date and to periodically inform the National Agrarian Authority about the compliance with the provisions of these Regulations within a period not exceeding sixty (60) days, which may be extended for the same period of time with due justification by the Licensee.

## GENERAL PROVISIONS

**FIRST.** - The National Agrarian Authority shall have the power to promulgate technical regulations, manuals of procedures, protocols, and instructions necessary to regulate the import, sowing, cultivation, harvest, post-harvest, storage, transportation, processing, marketing, and export of Non-Psychoactive Cannabis or Hemp, Non-Psychoactive

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Cannabis Derivatives or Hemp for Industrial Use or Hemp Derivatives for Industrial Use, including, but not limited to, the following:

- a.** Standards governing the safe production of Non-Psychoactive Cannabis or Hemp Derivatives.
- b.** Establish and modify formats and fees for applications and renewals.
- c.** Criteria for qualification and selection for licensing.
- d.** Limitations on the number of licenses to be granted.
- e.** Records that Licensees must create and maintain, including reports to be filed with the National Agricultural Authority and inspection of all records maintained by Licensees.
- f.** Procedures for hearings and additional grounds for cancellation, revocation and/or sanctions against any Licensee, in observance of the provisions set forth in the Organic Administrative Code.

**SECOND.** - The National Agrarian Authority shall request the inter-institutional support it considers necessary to carry out its respective monitoring and control functions, including the public forces, if applicable.

**THIRD.** - The Subsecretariat for Agricultural Production is delegated to issue, by means of Administrative Resolutions, the technical standards, procedural manuals, protocols, instructions and other instruments necessary for the application of these Regulations; for that purpose, it shall coordinate actions with the General Coordination of Strategic Planning and Management.

**FOURTH.** - The National Agrarian Authority, in coordination with the competent authorities, shall activate all the control and surveillance mechanisms, in order to identify all the Finished Products that are illegally commercialized, adopting the necessary measures and initiating the administrative processes applicable in each case.

### **TRANSITIONAL PROVISIONS**

**FIRST.** - Within a period of thirty (30) days as from the issuance of these Regulations, the General Coordination of National Agricultural Information shall create the National Registry of Licensees.

**SECOND.** - From the entry into force of this Regulation, AGROCALIDAD shall carry out the relevant processes established in the LOSA and other regulations, to start the pest risk analysis. Those interested in obtaining the License for the Importation and Commercialization of Non-Psychoactive Cannabis or Hemp Seeds, or Non-Psychoactive Cannabis or Hemp Cuttings or Non-Psychoactive Cannabis or Hemp Plants, or Hemp Seeds for Industrial Use, may start the process of registration of cultivars according to what is established in the LOASFAS and its regulations; and the phytosanitary procedures according to what is established in the LOSA and its regulations. Those interested who benefit from this transitory may not import Non-Psychoactive Cannabis Seeds or Hemp,

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or Non-Psychoactive Cannabis or Hemp Seedlings or Non-Psychoactive Cannabis or Hemp Plants, or Hemp Seeds for Industrial Use until they have the corresponding License.

**THIRD.** - Within one (1) year from the issuance of this Ministerial Agreement, the General Coordination of Information and Communication Technologies in coordination with the Undersecretary of Agricultural Production, will manage the implementation of the web and mobile platform for the control of the process of traceability of Non-Psychoactive Cannabis, according to the processes established, as determined by the functional needs of the Ministry of Agriculture and Livestock.

**FOURTH.** - The National Agrarian Authority will issue the corresponding tariff within thirty (30) days from the subscription of these Regulations for its correct execution.

### **FINAL PROVISION**

This Ministerial Agreement shall become effective as of the date of subscription, without prejudice to its publication in the Official Gazette.