

## **Legal framework for packaging and labeling of cannabis products and their derivatives.**

*The Cannabis Regulation Act approved in the Senate committees lays down specific rules for packaging and labeling of Cannabis products and their derivatives, which we explain in detail below.*

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### **I. Official Mexican Standards.**

The Official Mexican Standards ("NOM", in its Spanish acronym) are the technical regulations of mandatory observance issued by the competent authorities, aimed at the establishing requirements that must be complied with by the processes or services that may lead to people's health and safety hazards, as well as those related to terminology and referring to compliance and application.

The authorities in charge for the regulation or control of product, service, method, process or installation, activity or matter to be standardized, shall participate in its preparation, in exercise of their respective powers. Due to the nature of the law and that of the chapter applicable to packaging and labeling, the Ministries of Health, Environment and Natural Resources, Economy, Government, among other agencies, such as the Mexican Cannabis Institute or the Federal Commission for the Protection Against Sanitary Risks, shall participate in the creation of such NOMs. The competent authorities shall prepare the preliminary draft of the Official Mexican Standards and submit their content to the national standardization committees. The national standardization advisory committees, based on the preliminary drafts, shall prepare the draft of Mexican Official Standards.

For its preparation, they shall review whether there are related Standards such as NOM 142-SSA1/SCFI-2014 on alcoholic beverages, NOM-072-SSA1-2012 on labeling of medicines and herbal remedies, in order to elaborate jointly a single NOM per sector or subject to provide common practices (previously accepted) in those industries and apply them to the Cannabis industry to add the functionality and prior compression of the regulation to those integrating the industry.

The preliminary projects shall be accompanied by a regulatory impact analysis and the purpose of the standard, the proposed measures, the alternatives considered and the reasons for their rejection, a comparison of these measures with the regulatory background, as well as an overall description of the advantages and disadvantages and technical feasibility for verification of compliance with the standard.

As this is a new industry, and the cannabis production chain is to be regulated for the first time, the standard shall have a high impact on the economy or a substantial effect on a specific sector.

Therefore, the analysis must include monetary evaluation of the current value of the potential costs and benefits of the preliminary project and the alternatives considered, as well as, a comparison with international standards.

Since the regulation proposed in the preliminary project requires the use of specific materials, recipients of the Standard may request authorization from the authority issuing the Standard to use alternative materials, equipment, processes, test methods, mechanisms, procedures or technologies. The necessary scientific or objective evidence must be attached to the request, proving that the proposed alternative complies with the purposes of the respective standard.

### **II. Health Requirements.**

The regulation establishes what is the general sanitary information that the products must contain. Supposing, without conceding, that they are governed by this regulation:

The generic or specific name of the product, declaration of ingredients, identification and domicile of the manufacturer, importer, packer, national or foreign maquiladora or distributor, as the case may be, instructions for its conservation, use, preparation and consumption, components that could represent a mediate or immediate risk for the health of consumers, whether by ingestion, application or product manipulation, nutrimental input, expiration date, batch identification, the processing condition to which the product has been submitted, when the product is associating with potential risks, the precautionary legends and the warning legends.

Many of the aforementioned requirements are specifically defined in the preliminary project for the regulation of Cannabis.

- In regards to the legends, it is envisaged that the labeling must contain a legend appearing in large letters, describing the possible effects of the consumption of the product, which must occupy at least

50% of the main exposed surface of the product packaging.

- It must be pointed out, that its sale is allowed only within the Mexican territory, and only in case of holding an export license, the number of the license shall be indicated, as well as its registration data.
- The labels shall contain the following warning legend: "The consumption of this product is harmful to health. Adults between 18 and 25 years old, as well as pregnant or breastfeeding women are recommended to avoid its consumption."

Article 25 of the regulation provides that the standards relevant to each type of product shall determine the overall health information that must appear or to be specified on the label in case, due to the size of the packaging or the conditions of the process, it cannot contain all the required information. Regarding cannabis, these shall be the following:

- A. It must not contain explicit or subliminal images that evoke any emotion, feeling, state or style of life or any similar perception that implies associating them with the use or consumption of psychoactive cannabis and its derivatives;
- B. It must not contain logos that evoke the consumption of psychoactive cannabis and its derivatives;
- C. The type of cannabis used to make the product;
- D. THC and CBD levels;
- E. Labeling with the universal symbol THC, if applicable.

In case of imported packaged products of origin, the information contained in the labels must appear in Spanish, prior to marketing, in the terms of the applicable standard.

### **III. Cannabis Regulation Law.**

Article 26 of the law refers to the requirements that must be complied in order to intent the sale of cannabis products and their derivatives for recreational uses. Which are listed below:

1. They must be contained in a generic standardized packaging, ensuring in any case that they do not contain eye-catching colors or elements that may promote a brand, a product or its consumption, containing only the elements necessary to transmit the essential information to the consumer;
2. It must not expose testimonials or endorsements on the product, nor must it contain any representation of a real or fictitious person or character;
3. It must not contain explicit or subliminal images that evoke any emotion, feeling, state or style of life or any similar

feeling that implies associating them with the use or consumption of psychoactive cannabis and its derivatives;

4. It must not contain logos that evoke the consumption of psychoactive cannabis and its derivatives;
5. It must be made with sustainable materials, to be recyclable, biodegradable and compostable, approved by the competent authority;
6. It must be hermetic, resealable, child-proof and adolescent-proof, as well as to have a label containing a legend mentioning the prohibition of its consumption for children and adolescents;
7. It must indicate the number of the license, as well as its registration data;
8. It must indicate the registration number of the Ministry of Health;
9. It must indicate the type of cannabis used to make the product;
10. It must indicate the universal symbol THC, when applicable;
11. It must indicate THC and CBD levels;
12. The label must be of considerable size, with a legend in large letters, describing the possible effects of the consumption of the product, which must occupy at least 50% of the main exposed surface of the product packaging;
13. It must indicate that its sale is allowed only within the territory of the United Mexican States and only in case of holding an export license, the number of the license must be added, as well as its registration data, and
14. It must contain a unique high security visible control sign, mark or label, stating that it has complied with traceability standards.

15. Products with psychoactive cannabis content must contain on their label the following warning legend: "The consumption of this product is harmful to health. Adults between 18 and 25 years old, as well as pregnant or breastfeeding women are recommended to avoid its consumption."

Points 5 and 6 mentioned in the immediately preceding paragraph set forth requirements regarding the materials for the elaboration of products, and therefore, it is necessary to refer to other regulations such as the General Law for the

Prevention and Comprehensive Management of Waste and Regulations thereof. In this vein, articles 29 and 57 of the Law set forth the procedure for the products that, once they are discarded, must be sent to recycling and the treatments they plan to apply,

as well as the development of waste recycling that must be carried out in accordance with the legal provisions on environmental impact, risk, prevention of water, air and soil contamination, and others, that may be applicable.

In essence, the legal framework for the labeling and packaging of Cannabis products shall be developed once the Cannabis Regulation Law comes into force.

The content of the law to be promulgated shall lead to the elaboration of regulation resulting in Official Mexican Standards, as well as the inclusion of Cannabis in the Health Control of Products and Services Regulation with specific standards for its implementation, or perhaps a new regulation will be promulgated taking into consideration the characteristics of the aforementioned legal provision.

Based on the best practices and in line with the terms used by the Senators when using the wording "generic standardized packaging", it actually refers to a "neutral packaging" referred to by the World Health Organization as that which does not promote a product in a deceptive or misleading manner with regard to its characteristics, health effects, and that contains no terms, figurative or other signs that have a direct or indirect effect of creating false impression that a certain product is less harmful than other.

We are currently in an optimal moment for the adaptation and improvement of the law and for such modifications to be raised in the parliamentary discussions of the following

legislative period, possibly changing the content of the rules that, at first glance, seem to discourage entry to the industry. Likewise, the best practices contained in the various legal systems of countries with previous experiences such as Canada or pioneering North American States in this type of legislation could be implemented.

The purpose of the regulation is precisely to allow certain acts in the production and consumption chain for the transition from an illegal market to the legal market. The answer of legislators gives rise to a series of excessive requirements thinking that bad practices, corruption and the lack of application of the law can only be avoided by issuing more standards. We have countless examples demonstrating the opposite effect to that intended, by flooding the industry with regulations, requirements and formalities only at the beginning or before entering into commercial operations, which considerably affect the economic and legal development of our society. Such effects can be found

in the incorporation of companies, recycling, compliance, anti-money laundering and anti-corruption, among many other examples.

Overregulation is not only the excess of standards but also the development and issuance of standards aimless in their practical application that hinder the development of an activity becoming an impediment to entering the industry, producing a demotivating effect that leads to non-compliance with the rules. This problem will not only be faced by those seeking to enter the packaging and labeling industry, but also by the agencies that must authorize and monitor compliance with the law.

The question to be asked is whether the newly created Mexican Cannabis Institute will have the capacity and the human and economic resources to fulfill the powers it will be granted. Luis Guillermo Ibarra argues that "*The order of quotation of the levels in which overregulation affects public institutions is neither an error nor a coincidence. In our country, the regulatory aspect seems to precede the others. Often, the rule is created prior to considering the organization required for its application. This means that on many occasions, public institutions do not have the economic, organizational or human resources to enforce the rules, regardless of their intention or purpose*"<sup>1</sup>

We hope that the above information is useful to you, and we will be pleased to discuss any of the points addressed herein and clarify any doubts in this regard.

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#### **Pérez Ferrer Abogados, S.C.**

Javier Pérez Ferrer      [jperez@pfabogados.com](mailto:jperez@pfabogados.com)  
 Elías Lisbona Jassán      [elisbona@pfabogados.com](mailto:elisbona@pfabogados.com)

<sup>1</sup> Ibarra Guillermo Luis, Overregulation: a brake on development and cause of corruption. *Economic Seminar of Legal Studies*, p. 205.