Regulation, Trade and Standards Relating to Consumer Products Containing Hemp-Derived CBD

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Juan Antonio Dorantes & Danny Rubenstein

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Disclaimer

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Overview
Trends
and Statistics
Overview

*Cannabis sativa* is a versatile plant ("hemp" v. "marijuana") that is used for medical, recreational and industrial purposes – dependent on genetics of individual strains and agronomic conditions.

This presentation focuses exclusively on hemp and hemp-derived CBD

- Cannabidiolic acid (CBDA) is one of 100+ cannabinoid acids produced by *Cannabis sativa* spp., predominantly by hemp-type cultivars.

- Cannabidiol (CBD) is produced upon extraction and heating ("decarboxylation")

- CBD is non-psychoactive and *potentially* associated with pain control and health & wellness outcomes (*e.g.*, sleep and stress management), though evidence is limited.
Trends and Statistics

U.S. is Setting New Production Records with Broader Regulatory Approach and Cooperation:

• As a result of the 2018 Farm Bill (and previous state-based hemp pilot production programs), the U.S. is now producing more hemp than ever before.

• Peak acreage has grown rapidly from 146,000 acres (1943) to 500,000 acres (2019)  
  (Source: Hemp-Derived CBD Economic Viability Report (USDA ERS 2/20))

• Continued growth is anticipated in the near- to medium-term in all markets.
• Total U.S. market could potentially exceed $18-24 billion in 2024-25
  - Edibles ($6.9 billion (est.))
  - Food and beverage ($2.5 billion (est.))
  (Source: Brightfield, BDS Analytics, Canaccord)
Trends and Statistics

International forecasts show a similar trend:

- Total CBD sales in Europe estimated to exceed €1.5 billion in 2023
- UK total CBD market valued at $1.3 billion by 2025
  (Source: Brightfield, BDS Analytics, Canaccord)

Distribution channels likely to vary:

- “Brick and Mortar” sales have surpassed online sales of CBD products, due to the entrance of retail, grocery and pharmacy chains
- 57% of sales were conducted through retail and 22% were online in 2019
  (Source: Brightfield Group)
- Expect additional entrants: pet stores, gyms, etc. in near future...
Mexican Regulation of CBD
Mexican Regulation of CBD

1 - History of CBD Regulation
2 - Controlling Laws and Regulations prior to 2020
3 - Lawsuit Result
4 - Proposed Regulation Health Control
5 - The future of CBD Regulations in Mexico
## History of CBD Regulation

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1961</td>
<td>The first international prohibition of cannabis is established in the Single Convention on Narcotic Drugs of 1961, classifying it as &quot;highly addictive&quot; and with &quot;wide potential for abuse&quot;, as well as its &quot;limited&quot; &quot;non-existent&quot; therapeutic use.</td>
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<td>1971</td>
<td>Psychotropic Substances Convention creates 4 levels of classification, leaving THC in fraction 1 (recommended control for possible abuse and damage to public health, as well as null or non-existent therapeutic value)</td>
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<tr>
<td>1988</td>
<td>Convention against illicit drug trafficking strengthens the prohibition by classifying as crimes the production, manufacture, distribution, sale, transport, import or export of any narcotic or psychotropic, as well as the production of the cannabis plant</td>
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<td>2017</td>
<td>At a meeting of the WHO Expert Committee on Drug Dependence (ECDD) it was concluded, through various analyzes and trials, that CBD is safe and well tolerated by humans. They also stated that it has no potential for abuse and that it has very few side effects, and those that it can produce are minor. However, the WHO made sure not to recommend CBD for medicinal uses, recognizing that more studies are needed in this area.</td>
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<tr>
<td>2018-2019</td>
<td>Reform of the General Health Law</td>
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<td>2018-2019</td>
<td>Guidelines on health control of cannabis and derivatives of the same</td>
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<tr>
<td>2018-2019</td>
<td>In February 2020, the Chamber of Senators generally voted IN FAVOR of the General Law on Cannabis and its derivatives.</td>
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Lawsuit Result

There are 2 outstanding lawsuits in Mexico related to CBD and cannabis:

1. 2015 SCJN dictates judgment in order to remove the prohibition of cannabis and derivatives for medical purposes of the GHL, in the Grace’s case.

2. 2015 SCJN dictates judgment for the recreational use of marijuana includes: sowing, cultivating, harvesting, preparing, possessing, transporting and consuming, without harming third parties and without commercialization purposes.
Controlling Laws and Regulations Prior to 2020

• Federal Drug Addiction Regulation (1939)

• Health General Law

• Regulation of Health Products

• Regulation of Sanitary Control of Products and Services

• Guidelines on health control of cannabis and derivatives
Proposed Regulation Health Control

July 2020  Regulation on Health control for the production, research and medicinal use of cannabis and its pharmacological derivatives

- Only allows medicinal and research uses
- Define CBD as a non-psychotropic substance
- Sowing, growing and harvesting are only authorized for medicine and research
- Does not define industrial use of non-psychoactive cannabis
Proposed Regulation Health Control

April 2020 General Law for the Regulation of Cannabis

- Only allows medicinal, industrial and research uses
- Define CBD as a non-psychotropic substance
- Sowing, growing and harvesting are only authorized for industrial, medicinal and research purposes
- Does not define industrial use of non-psychoactive cannabis
- Issues criteria for labeling and advertising
Mexico is at a regulatory impasse: The government's intentions are to regulate CBD as a controlled substance, but leave hemp without adequate regulation by equating it with psychoactive cannabis.
Regulation of CBD in the United States
History of Federal Regulation

• Prior to 2014: illegal under federal law to grow, cultivate, market, or distribute any part of the *Cannabis sativa* L. plant.

• *Cannabis sativa* L. plant = "all parts... whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin." See 21 U.S.C. § 802(16).

• Marijuana and hemp are both members of the *Cannabis sativa* family, and CBD is a derivative (extract) that can be obtained from either plant.

• Marijuana contains delta-9 tetrahydrocannabinol (THC), a psychoactive agent, at varying concentrations (influenced by genetic profile of the plant, specific growing conditions); hemp typically contains significantly lower levels of THC – and, depending on the variety, substantial levels of CBD.
History of Federal Regulation

• Marijuana is a Schedule I substance under the Controlled Substances Act (CSA), the most restrictive category of controlled substances.

• The CSA prohibits the manufacture or distribution of Schedule I-controlled substances without prior registration with/approval by the Drug Enforcement Administration (DEA) (Pub. L. 91-513 (1971); 21 U.S.C. ch. 13 § 801 et seq.)

• In the absence of regulation to the contrary, and despite the fact that marijuana and hemp differ in terms of the presence or absence of significant levels of THC, respectively, both variations of the *Cannabis sativa* L. plant were regulated in a nearly identical fashion at the federal level prior to 2014.
2014 Farm Bill – Pilot Program

• The 2014 Farm Bill granted special authority by Congress for states to permit the growing and cultivation of industrial hemp under an “agricultural pilot program or under agricultural or academic research” under the CSA...

• ...provided that the growth and cultivation of industrial hemp was otherwise authorized – typically by an implementing Act or regulation – under state law.

• Industrial hemp is defined under the Farm Bill as hemp containing less than 0.3% THC on a dry weight basis, as this threshold of THC content is defined by the federal government as the threshold that is generally considered insufficient to cause a narcotic effect.
2014 Farm Bill – Pilot Program

- *Industrial hemp* was (and remains) defined under the Farm Bill as hemp containing **less than 0.3% THC on a dry weight basis**, as this threshold of THC content is defined by the federal government as the threshold that is generally considered insufficient to cause a narcotic effect.
2018 Farm Bill and Regulatory Changes

• Confusion in the marketplace continued between 2014-2018...
  - States wanted to expand industrial hemp production beyond pilot programs
  - Access to federally-regulated entities (financial banking system) remained limited

• 2018 Farm Bill removed hemp and *de minimis* levels of THC in hemp from the statutory definition of marijuana under the Controlled Substances Act; stated unambiguously that interstate transportation of hemp (including seeds and derivatives) is legal.

• Moving forward, hemp no longer Schedule I; marijuana remains listed under Schedule I and illegal under federal law.

• **New Development**: DEA Interim Final Rule – THC must not exceed 0.3% *at any point in the manufacturing process*. Hemp Industry Association (HIA) Lawsuit pending.
FDA Regulation of Hemp-Derived CBD

Under existing Federal framework, multiple agencies have jurisdiction, including FDA.

FDA has made the following clear:

1. The Agency intends to regulate CBD
2. FDA will regulate CBD the same way that it would any other substance
3. Regulation will follow a risk-based, scientifically-supported approach

...but FDA also recognizes that the marketplace is evolving rapidly, and regulation often lags behind advances and innovation. Federal resources are limited.

The Bottom Line:  
*Tread Carefully.*
Don’t assume all products are lawfully marketed!
FDA Regulation of Hemp-Derived CBD

Types of Regulated Products

- **Food**: Three Generally Recognized as Safe (GRAS) ingredients – that’s it!

- **Dietary Supplements**: None currently authorized by FDA

- **Drugs**: One specific authorization (Epidiolex®)
  - Clinical studies and approval foreclosed self-determined GRAS option for food

- **Cosmetics**:
  - Generally not subject to premarket approval by FDA...
  - Except for the use of color additives in the manufacture of a finished cosmetic.
  - Instead, cosmetics are simply “regulated” by FDA and ingredients must be safe.
  - Safe = not *adulterated or misbranded*, as those terms are defined under the FD&C Act
FDA Regulation of Hemp-Derived CBD

The Path of Least Resistance (?) – Food and Cosmetics

- Hemp seed-derived products (dehulled hemp seeds, hemp seed protein, and hemp seed oil), which contain de minimis levels of CBD, are considered Generally Recognized as Safe (GRAS). They may currently be lawfully marketed in human food without the need for any further FDA authorization.

- Some companies considering alternative formulations (i.e. topical products) as a way to enter the market while waiting for food and beverage obstacles to be reduced/eliminated.

- Some companies are beginning to market alternative non-psychoactive cannabinoids with similar properties to CBD (i.e., CBG, CBC), but risks remain...

- Research into alternative sourcing for phytocannabinoid production has started.
FDA Regulation of Hemp-Derived CBD

Claims Matter!

Adulterated:
If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling.

Misbranded:
False or misleading labeling. But claims matter not only because of misbranding, but also because of product positioning:

✓ Structure/Function claims (“CBD improves ____”) = dietary supplement
✓ Diagnose/treat/cure/prevent a disease (“CBD cures ____”) = drug

Products intended as cosmetics could become dietary supplements or drugs by virtue of product labeling – FDA will enforce as such.
FDA Regulation of Hemp-Derived CBD

Enforcement Activities

Warning letters used as primary enforcement activity (quick, simple, effective, and very visible from a public standpoint)

Agency focus on claims:
- Products that purport to function as dietary supplements or drugs not permitted
- FDA will state affirmatively that products “appear to be unapproved _____”
- Remedial action usually involves amending product labels and claims; occasional withdrawal

Agency focus on sensitive subpopulations:
- Advertising that targets vulnerable – sick, elderly, children
- Coordination with Federal Trade Commission and state agencies
State Regulation

- 2018 Farm Bill expanded state pilot programs originally authorized under 2014 Farm Bill;

- Elimination of hemp-derived CBD from Schedule I opened the door to state regulation without directly conflicting with federal law.

- Federal regulation is effectively a “floor,” not a “ceiling.”
State Regulation

- Some states have taken a cautious approach (limited agricultural programs, often in conjunction with academic or institutional facilities with state funding or oversight)
- Other states have taken a more progressive approach (authorizing uses that go above and beyond FDA regulated uses, “when FDA catches up”)
- State enforcement also varies widely – certain products on the market with implicit state sanction; despite federal restrictions. Other states enforce federal restrictions aggressively. Some inconsistencies in understanding of FDA regulation at the state level.
Things to Consider...

Even where product labeling and advertising otherwise complies with FDA requirements for cosmetics, there remains significant uncertainty as to the analytical method and validation of products that “contain less than 0.3% THC.”

Industry continues to struggle with questions such as:

(1) the definition of “dry weight basis” (e.g., is this measured on the basis of the CBD additive, or the finished product?)

(2) analytical testing capabilities and limitations (e.g., is there a “bright line” limit at 0.3%, or is certain variability permitted between products or batches? If the latter, how much variability is acceptable?)

(3) product labeling (despite the relaxing of regulatory requirements pertaining to the shipment of CBD, various litigation risks remain with regard consumer deception and claims and advertising that may change a product’s regulated status from a cosmetic to a dietary supplement or drug.

(4) New: DEA regulation and interpretation of 0.3% THC content threshold during manufacture/production.
Looking Ahead

• The demand for CBD products will continue to climb - despite offsets in supply (such as the poor 2019 hemp production season and COVID-related disruption this year)

• Product innovation will likely continue to outpace regulation (for now); FDA will focus resources on most significant perceived health and safety risks, and “high profile wins”

• States will act in the absence of Federal Government leadership, but preemption issues likely to remain top of mind

• Potential change in administration may change overall posture and regulatory structure...

• Federal Government and States still “learning as we go.”
Trade Considerations
Draft Regulation in Mexico

The Preliminary Draft Regulation on Health Control for the production, research, and medical use of cannabis and its pharmacological derivates was notified by Mexico to the Committee of Technical Barriers to Trade on September 9, 2020.

- Established a period of 60 days prior its notification for the presentation of comments.
- The deadline is on November 8, 2020.
- G/TBT/N/MEX/475

CONAMER’s Preliminary ruling
- Document CONAMER/20/3246
- August 25, 2020

CONAMER’s Final ruling
- Document CONAMER/20/3284
- August 26, 2020

63 Comments
- AMMCann A.C.
- AROCHI & LINDNER, S.C.
- AMEM
- Instituto RIA
- Mexico papers
- Grupo Promotor de la Industria de Cannabis
Relevant WTO Obligations

General Agreement on Tariffs and Trade 1994 (GATT 1994)

Agreement on Import Licensing Procedures

Agreement on Technical Barriers to Trade (TBT Agreement)

Agreement on Agriculture

General Agreement on Trade in Services (GATS)

Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

Agreement on Trade Facilitation
# Main WTO-Related Provisions

## GATT 1994

- Article I: General Most-Favored Nation Treatment
- Article III: National Treatment on Internal Taxation and Regulation
- Article X: Publication and Administration of Trade Regulations
- Article XI: General Elimination of Quantitative Restrictions
- Article XX: General Exceptions

## GATS

- Article I: Scope and Definition
- Article II: Most-Favored Nation Treatment
- Article VI: Domestic Regulation
- Article XIV: General Exceptions

## SPS Agreement

- Article 2: Basic Rights and Obligations
- Article 3: Harmonization
- Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection
- Article 8 Control, Inspection and Approval Procedures
- Annex C Control, Inspection and Approval Procedures
## Main WTO-Related Provisions

### Agreement on Trade Facilitation
- Article 7: Release and Clearance of Goods
- Article 8: Border Agency Cooperation
- Article 10: Formalities Connected with Importation, Exportation and Transit
- Article 12: Customs Cooperation

### Agreement on Agriculture
- Article 2 Product Coverage
- Article 6 Domestic Support Commitments
- Article 12 Disciplines on Export Prohibitions and Restrictions

### TBT Agreement
- Article 1 General Provisions
- Article 2 Preparation, Adoption and Application of Technical Regulations by Central Government Bodies
- Article 3 Preparation, Adoption and Application of Technical Regulations by Local Government Bodies and Non-Governmental Bodies
- Article 4 Preparation, Adoption and Application of Standards
- Article 5 Procedures for Assessment of Conformity by Central Government Bodies
- Article 6 Recognition of Conformity Assessment by Central Government Bodies
- Article 7 Procedures for Assessment of Conformity by Local Government Bodies
- Article 8 Procedures for Assessment of Conformity by Non-Governmental Bodies
- Annex 3 Code of Good Practice for the Preparation, Adoption and Application of Standards

### Agreement on Import Licensing Procedures
- Article 1: General Provisions
Relevant USMCA Obligations

2. National Treatment and Market Access
3. Agriculture
9. Sanitary and Phytosanitary Measures
11. Technical Barriers to Trade
12. Sectoral Annexes
20. Intellectual Property
21. Competition Policy
28. Good Regulatory Practices
Relevant USMCA Obligations

11.4: International Standards, Guides and Recommendations

11.5: Technical Regulations

12.1: Sectorial Annexes

28.15: Information About Regulatory Processes

28.17: Encouragement of Regulatory Compatibility and Cooperation

9.7: Enhancing Compatibility of Sanitary and Phytosanitary Measures

9.6: Science and Risk Analysis

9.9: Equivalence

3.5: Export Restrictions – Food Security

Article 2.4: Treatment of Customs Duties

Article 2.3: National Treatment

2.11: Import and Export Restrictions
International Organizations

World Health Organization (WHO)
- Recommendations presented by the Director General of WHO to the UN Secretary General and the United Nations Commission on Narcotic Drugs (CND).
- Expert Committee on Drug Dependence (ECDD)
- Department of Essential Medicines and Health Products (EMP)
- *International Drug Control Conventions*

Codex Alimentarius (FAO)
- Joint FAO/WHO FOOD STANDARDS PROGRAMME CODEX Committee on Pesticide Residues 50th Session Haikou, PR. China, 9 - 14 April 2018 Revision of the Classification of Food and Feed: Class A: Primary Food Commodities of Plant Origin

UN Commission on Narcotic Drugs (CND)
- Policymaking body of the United Nations system with prime responsibility on narcotic drugs
International Organizations

- European Industrial Hemp Association
- International Hemp Building Association
- Hemp Industries Association
**Tariff Lines**

**COFEPRIS Circular T-218/18**

- **38 Products with cannabis**
- **Food supplements, cosmetics, food and raw material**

**Importation and exportation**

- 12079901 - Hemp (cannabis sativa)
- 53021001 - Raw or retted hemp
Importance of International Standards Development

• Given that international trade obligations generally require the use of relevant international standards, in whole or in part, as the basis for technical regulations, it is important for stakeholders to encourage jurisdictions to incorporate such standards into their technical regulations
  
  o Use of relevant international standards improves the quality of regulation: it incorporates provisions that reflect the expertise and consensus views of producers, equipment providers, consumers, government officials, TIC service providers, and other stakeholders

  o Use of relevant international standards is trade facilitative: it promotes regulatory alignment and helps avoid the creation of trade barriers and unnecessary regulatory differences

• It is also important for stakeholders to participate in standards development work so that they can provide input to help shape the content of the resulting standards.
Relevant Standards Development Activities

• ASTM International: established Committee D37 on Cannabis in 2017

• Scope of Work: cannabis (both products and processes)

• Membership: more than 600 persons from 25 countries

• Technical subcommittees (TCs): eight, plus an executive committee and a terminology committee
  - Includes TCs covering industrial hemp; security and transportation; laboratories; quality management systems; devices and appliances; personnel training, assessment, and credentialing; packaging and labeling; water activity
  - Three layers of work: task group, subcommittee and full committee
  - At least a dozen finalized international standards and three dozen standards under development
  - Also developing a third party certification system to enable firms to demonstrate compliance with ASTM standards across jurisdictions

• No cannabis-specific ISO standards, but many ISO standards are relevant, e.g., management systems standards and standards relating to testing and calibration labs, inspection bodies, certification bodies, accreditation bodies, and audits

• Upcoming ASTM workshop on October 22-23 featuring panels on: sharing regional updates from around the world, brainstorming on necessary standards for test methods, and discussion on working cannabis/hemp issues into the UN SDGs
Relevant Intergovernmental Activity

- World Health Organization: in 2019, the [WHO Expert Committee on Drug Dependence (ECDD)](https://www.who.int) issued recommendations to the UN Commission on Narcotic Drugs (CND).

- Among them was a recommendation that the CND should relax the classification of cannabis under the Single Convention on Narcotic Drugs and clarify that “Preparations containing predominantly cannabidiol and not more than 0.2 percent of delta-9-tetrahydrocannabinol [THC] are not under international control.”

- The CND is meeting in December 2020 to consider the ECDD recommendations.
Relevant Intergovernmental Activity

• A group of hemp trade associations – including from the Asia-Pacific, Australia, Canada, Europe, Japan, Latin America, Mongolia, New Zealand, the UK, and the US- -- have put forward a “Common Position of the Industrial Hemp Sector on the Single Convention and the International Drug Control System” in advance of the December meeting.

• Key recommendation: “Industrial Hemp (or “hemp”) should be defined as “a Cannabis sativa L. plant - or any part of the plant - in which the concentration of tetrahydrocannabinol (THC) in the flowering or fruiting tops is less than the regulated maximum level, as established by authorities having jurisdiction.”

• Mexico is a member of the CND and has a vote.
Potential Opportunities