Cannabis and CBD in the Food and Dietary Supplement Industries

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Moderated by **Justin Prochnow**, Greenberg Traurig, LLP

FDLI

Justin J. Prochnow

- **Justin J. Prochnow is a shareholder in the Denver office of the international law firm Greenberg Traurig. Justin is co-chair of GT's Food, Beverage, and Agribusiness practice and his practice focuses on assisting companies with regulatory, business, and legal needs in the beverage, food, dietary supplement, cosmetic, medical device, and OTC industries.**
- **Justin's practice includes:**
  - Review of product labels, labeling, advertising, websites and other marketing materials for compliance
  - Responding to governmental and regulatory actions, including FDA inspections and warning letters and FTC Civil Investigative Demands
  - Preparing business documents for industry members, including consulting, manufacturing, supply and distribution agreements
  - Defending industry companies from both governmental agencies and civil litigators in litigation ranging from breach of contract cases to the growing number of class actions alleging false and misleading advertising

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Cannabis and Food: What Are the Rules of the Road?

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Co-Chair, Cannabis Law
SAUL EWING ARNSTEIN & LEHR LLP
FDLI Food Advertising, Labeling, and
Litigation Conference
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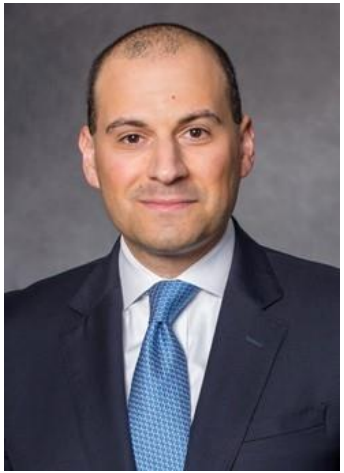
Jonathan A. Havens

Jonathan Havens is co-chair of the Cannabis Law Practice at Saul Ewing Arnstein & Lehr LLP. He also serves as vice chair of the firm's Food and Beverage Practice and is a member of the firm's Life Sciences Practice. Jonathan's unique perspective on cannabis regulation is informed by his congressional, federal agency, and national and international law firm experience.

He counsels state cannabis license applicants and awardees, ancillary service and product providers, investors, management companies, and various other entities that are affected by federal and state marijuana laws, such as long-term care facilities and higher education institutions.

Before entering private practice, Jonathan served as a regulatory counsel with the U.S. Food and Drug Administration (FDA), where he focused on compliance and enforcement related to promotion, advertising, and labeling. Prior to law school, Jonathan held legislative and government affairs positions in which he managed several areas of policy and drafted legislative proposals, and facilitated the development and execution of strategic communications to members of Congress and their staff aides.



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What is the regulatory status of cannabis?

- More than 50 percent of states have medical cannabis laws on the books.
- Nine states with medical cannabis laws have also legalized recreational or "adult use" cannabis.
  - Alaska, California, Colorado, Maine, Massachusetts, Nevada, Oregon, Vermont, and Washington.
  - Possession of up to two ounces of recreational marijuana is legal in Washington, D.C., but *sales* are not legal.
- Other states are considering establishing such programs.
- However, marijuana is still illegal under federal law.
  - It is a Schedule I drug under the Controlled Substances Act (21 U.S.C. § 812(b)(1)).

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What ~~is~~ was the Cole Memo?

The U.S. Department of Justice (DOJ) issued a memorandum in 2013 (Cole Memo), which:

- Said that state laws do not change marijuana's illegal status under federal law; and
- Directed U.S. Attorneys to utilize their resources prudently, and to use discretion before prosecuting those using medical marijuana in compliance with their state's laws.

The Cole Memo represented a major shift in drug enforcement, and after its issuance, federal marijuana prosecutions declined in states that had authorized certain marijuana activity.

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Rescission of Obama-Era Marijuana Enforcement Policies

- On January 4, 2018, Attorney General Jeff Sessions issued a memorandum to all U.S. Attorneys in which he rescinded, effective immediately, several previous U.S. Department of Justice (DOJ) guidance documents related to marijuana enforcement, including the Cole Memo.
- He also rescinded:
  - David W. Ogden, Deputy Att'y Gen., Memorandum for Selected United States Attorneys: Investigations and Prosecutions in States Authorizing the Medical Use of Marijuana (Oct. 19, 2009);
  - James M. Cole, Deputy Att'y Gen., Memorandum for United States Attorneys: Guidance Regarding the Ogden Memo in Jurisdictions Seeking to Authorize Marijuana for Medical Use (June 29, 2011);
  - James M. Cole, Deputy Att'y Gen., Memorandum for All United States Attorneys: Guidance Regarding Marijuana Related Financial Crimes (Feb. 14, 2014); and
  - Monty Wilkinson, Director of the Executive Office for U.S. Att' ys, Policy Statement Regarding Marijuana Issues in Indian Country (Oct. 28, 2014).

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The U.S. Food and Drug Administration (FDA)

- Although it has not been well publicized, FDA has said quite a bit about cannabis:
  - FDA and Marijuana: Questions and Answers: http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#enforcement.
  - Marijuana Research with Human Subjects: http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421173.htm.
  - FDA and Marijuana: http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421163.htm.
  - CBD Warning Letters: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm549298.htm (2017); http://www.fda.gov/newsevents/publichealthfocus/ucm484109.htm (2016).

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FDA (cont'd)

- Some highlights:
  - "Why hasn't the FDA approved marijuana for medical uses?... To date, the FDA has not approved a marketing application for marijuana for any indication…The FDA has approved Epidiolex, which contains a purified drug substance cannabidiol, one of more than 80 active chemicals in marijuana, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.
    - FDA approved GW Pharmaceuticals' New Drug Application (NDA) for Epidiolex (cannabidiol) on June 25, 2018. See https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm.
  - "Can products that contain cannabidiol [CBD] be sold as dietary supplements?...No."
  - "Is it legal, **in interstate commerce**, to sell a food to which THC or CBD has been added?...No." (emphasis added).

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FDA (cont'd)

12. Can products that contain THC or cannabidiol (CBD) be sold as dietary supplements?

A. No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, respectively. Under those provisions, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 (section 505 of the FD&C Act), or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

There is an exception to sections 201(ff)(3)(B)(i) and (ii) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD. For more information on this provision, including an explanation of the phrase "marketed as," see Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues.

FDA is not aware of any evidence that would call into question its current conclusions that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not called our conclusions into question.

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FDA (cont'd)

13. Is it legal, in interstate commerce, to sell a food to which THC or CBD has been added?

A. No. Under section 301(ll) of the FD&C Act, it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 (section 505 of the Act) or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added. FDA is not aware of any evidence that would call into question these conclusions. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not called our conclusions into question.

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FDA (cont'd)

- Highlights (continued):
  - "FDA Supports Sound Scientific Research…The FDA also has an important role to play in supporting scientific research into the medical uses of marijuana and its constituents in scientifically valid investigations as part of the agency's drug review and approval process. As a part of this role, the FDA supports those in the medical research community who intend to study marijuana."
  - "Is marijuana safe for medical use?…The study of marijuana in clinical trial settings is needed to assess the safety and effectiveness of marijuana for the treatment of any disease or condition."
  - "Does the FDA object to the clinical investigation of marijuana for medical use?…No. The FDA believes that scientifically valid research conducted under an IND application is the best way to determine what patients could benefit from the use of drugs derived from marijuana."

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FDA (cont'd)

- Highlights (continued):
  - "What is FDA's reaction to states that are allowing marijuana to be sold for medical uses without the FDA's approval?... The FDA is aware that several states have either passed laws that remove state restrictions on the medical use of marijuana and its derivatives or are considering doing so. It is important to conduct medical research into the safety and effectiveness of marijuana products through adequate and well-controlled clinical trials."
  - "Does the FDA object to the clinical investigation of marijuana for medical use?...No. The FDA believes that scientifically valid research conducted under an IND application is the best way to determine what patients could benefit from the use of drugs derived from marijuana."

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FDA (cont'd)

- Highlights (continued):
  - "Will FDA take enforcement action regarding THC and CBD products that are marketed as dietary supplements? What about foods to which THC and CBD has been added?...When a product is in violation of the FD&C Act, FDA considers many factors in deciding whether or not to initiate an enforcement action. Those factors include, among other things, agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action."
  - "What is the effect of section 7606 of the Agricultural Act of 2014 (sometimes known as the "industrial hemp" provision of the Farm Bill) on the FD&C Act?...[S]ection 7606 did not amend the FD&C Act. For example, section 7606 did not alter the approval process for new drug applications, the requirements for the conduct of clinical or nonclinical research, the oversight of marketing claims, or any other authorities of the FDA as they are set forth in that Act. All products must comply with any relevant provisions of the FD&C Act."

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U.S. Drug Enforcement Administration (DEA)

- DEA is a federal agency under the Department of Justice (DOJ) that enforces the Controlled Substances Act (CSA).
- Marijuana is a Schedule I substance under the CSA.
  - Schedule I drugs are classified as having a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use of the drug or other substance under medical supervision.
  - Marinol, a synthetic version of THC (delta-9-tetrahydrocannabinol), the active ingredient found in the marijuana plant, can be prescribed for the control of nausea and vomiting caused by chemotherapeutic agents used in the treatment of cancer and to stimulate appetite in AIDS patients. Marinol is a Schedule III substance under the Controlled Substances Act.

DEA (cont'd)

- Now that FDA has approved Epidiolex®, the drug is subject to DEA scheduling, a decision which industry will follow closely.
- It will be interesting to see how DEA schedules Epidiolex®, particularly in light of GW Pharmaceuticals' completion of a clinical trial assessing the abuse potential of CBD in October 2017.
- If DEA believes Epidiolex® has a low potential for abuse and low risk of dependence, it could schedule the drug as Schedule IV.

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DEA (cont'd)

- In August 2016, DEA declined to reschedule marijuana.
- In February 2017, DEA removed from its website factually inaccurate information about cannabis. Americans for Safe Access ("ASA"), a nonprofit focused on ensuring access to medical cannabis for therapeutic use and research, filed with the U.S. Department of Justice ("DOJ") last year a legal request demanding such action, and started a change.org petition related to the same (which has over 104,000 signatures).
- In March 2017, DEA approved Syndros, a synthetic formulation of THC, the main psychoactive component in the cannabis plant. FDA approved the drug in 2016 to treat nausea, vomiting, and weight loss in cancer and AIDS patients.

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Let's Talk About Hemp

- Hemp comes from the same species of plant, *Cannabis sativa L.*, as marijuana (this is why production is restricted in the U.S).
- Congress made significant changes to federal policies regarding hemp in the 2014 farm bill (Agricultural Act of 2014 (P.L. 113-79, §7606).
- The 2014 farm bill provided that certain research institutions and state departments of agriculture may grow hemp under an agricultural pilot program.
- The bill further established a statutory definition for industrial hemp as "the plant *Cannabis sativa L.* and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

Source: Congressional Research Service

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Let's Talk About Hemp (cont'd)

- Common misconceptions: industrial hemp is legal in all 50 states; lack of enforcement = legality.
- Fact: Under current U.S. drug policy, all cannabis varieties —including industrial hemp — are considered Schedule I controlled substances under the Controlled Substances Act (CSA, 21 U.S.C. §§801 *et seq*.).
- If industrial hemp is "legal" (*i.e*., not Schedule I), as many claim it is, why did Senator Mitch McConnell offer an amendment to the 2018 Farm Bill to clarify that the term "marihuana" in the CSA does not include industrial hemp?
  - Hemp legalization is addressed in the Senate's version of the Farm Bill, but not the House's. This issue will be addressed in conference. McConnell is one of the conferees.
- DEA's position is that the commercial sale or interstate transfer of industrial hemp is restricted.

Source: Congressional Research Service

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Let's Talk About Hemp (cont'd)

- Hemp-derived CBD is widely available (brick-and-mortar and online), and not just for humans (CBD for pets is gaining popularity).
- The widespread availability of hemp-derived CBD suggests that not all of it is derived from hemp grown under state pilot programs.
- There has been enforcement *(e.g.*, raids and seizures), but it is sporadic.
- While some believe hemp-derived CBD is lower risk than cannabis-derived CBD, to DEA, such products might be a distinction without a difference.
- Take a few minutes to read the 9th Circuit's unpublished order in *Hemp Industries Assoc. v. U.S. Drug Enforcement Administration, et al.* (https://cdn.ca9.uscourts.gov/datastore/memoranda/2018/04/30/17-70162.pdf).
  - The court denied HIA's petition seeking review of the DEA's Final Rule establishing a new drug code for marijuana extract that went into effect on January 13, 2017.
  - The decision was mostly on procedural grounds (HIA did not submit comments to DEA's docket).

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Hemp in Foods

- A blast from the past: Hemp-Food Firms Fight U.S. Ban, Deny Marijuana Link (Washington Post, 2002): https://www.washingtonpost.com/archive/politics/2002/01/13/hemp-food-firms-fight-us-ban-deny-marijuana-link/4bcb4401-f119-432b-adeb-192f72fbdd32/?utm_term=.3bfdd4f48ca8.
- Some other interesting reading:
  - Cannabis Comes to Your Coffee and Candy—But Is It Legal? (https://www.wsj.com/articles/cannabis-comes-to-your-coffee-and-candybut-is-it-legal-1536761536) ("In 2014, a federal farm bill let states start pilot programs to study the growth, cultivation and marketing of hemp. Some companies interpreted that as a green light to sell CBD-containing products.")
  - Brand of granola bars contains hemp seeds, Army warns (https://www.armytimes.com/news/your-army/2015/08/11/brand-of-granola-bars-contains-hemp-seeds-army-warns/)
  - Evaluating the impact of hemp food consumption on workplace drug tests (https://www.ncbi.nlm.nih.gov/pubmed/11765026)

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Questions?

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Food Safety in Cannabis Infused Products

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Eastern Food Safety, Inc. **9.27.18**

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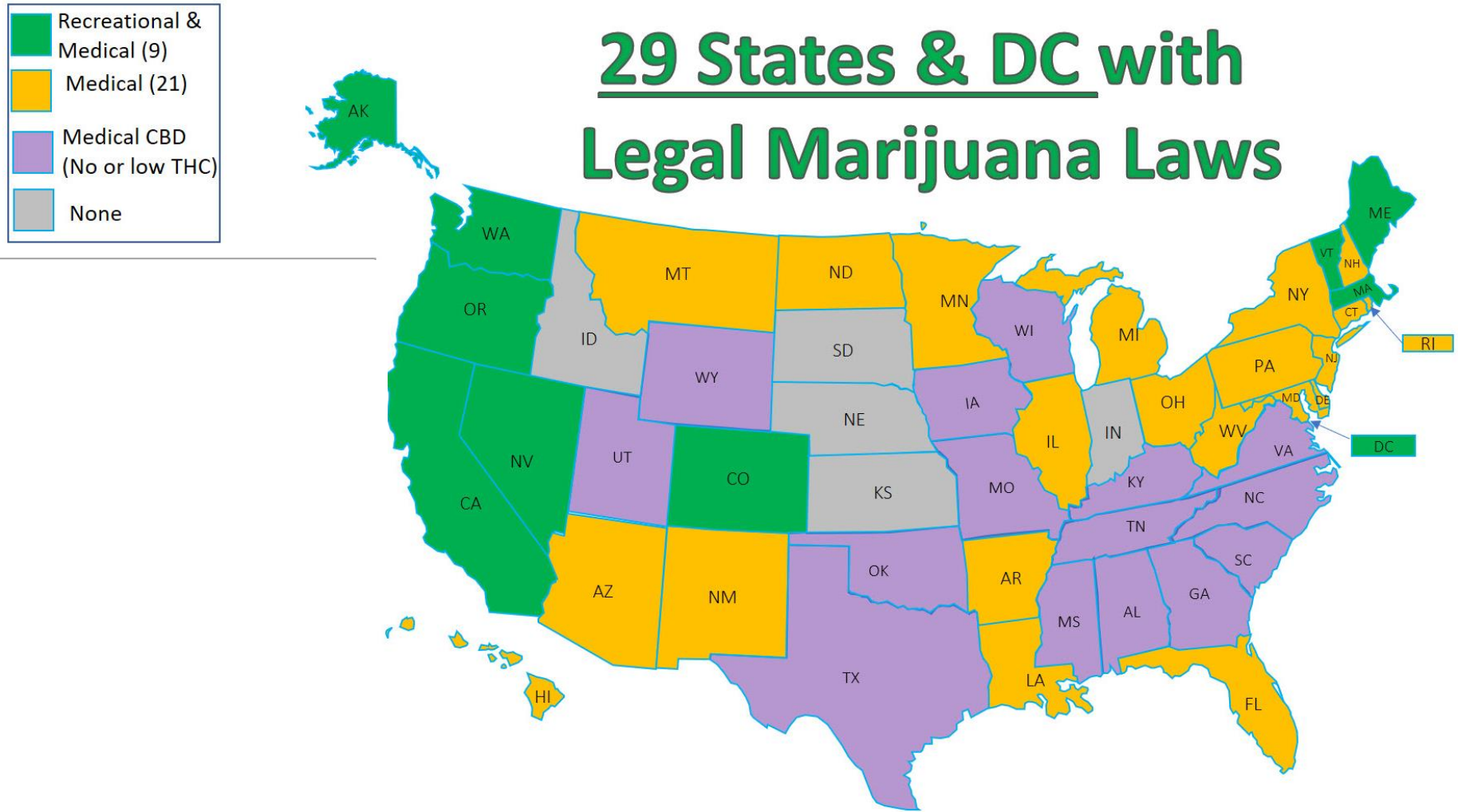
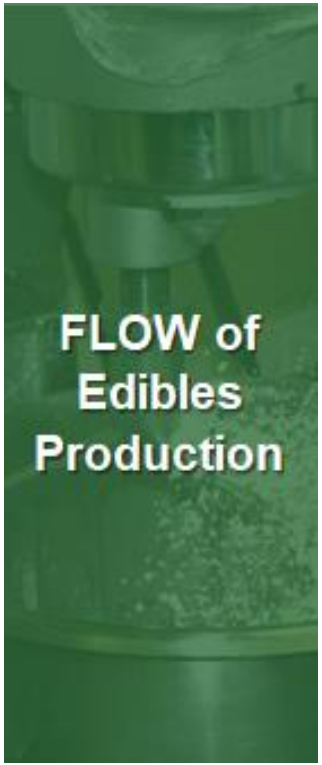
29 States & DC with Legal Marijuana Laws



Hazard Analysis Critical Control Point system



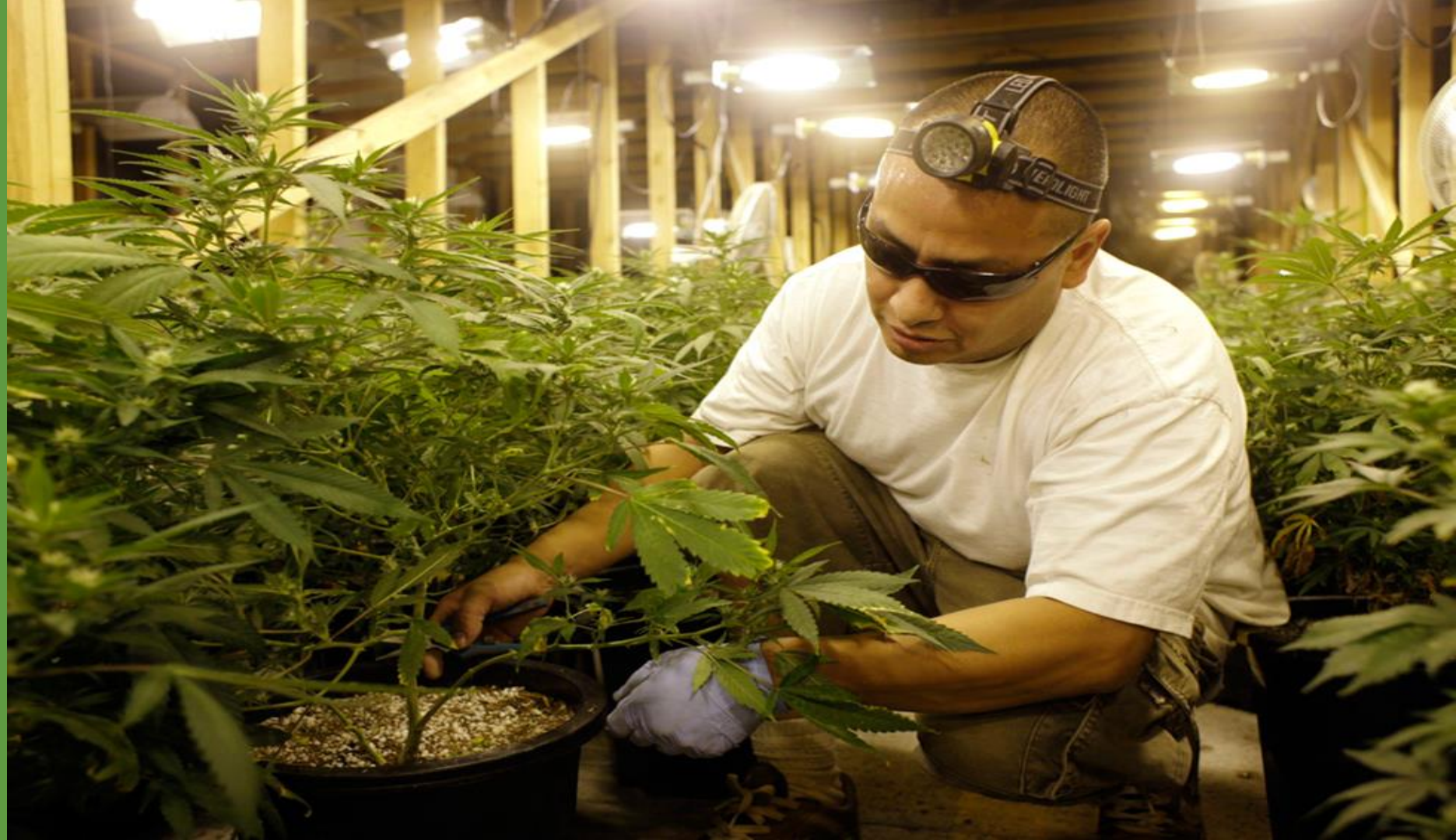
Growing

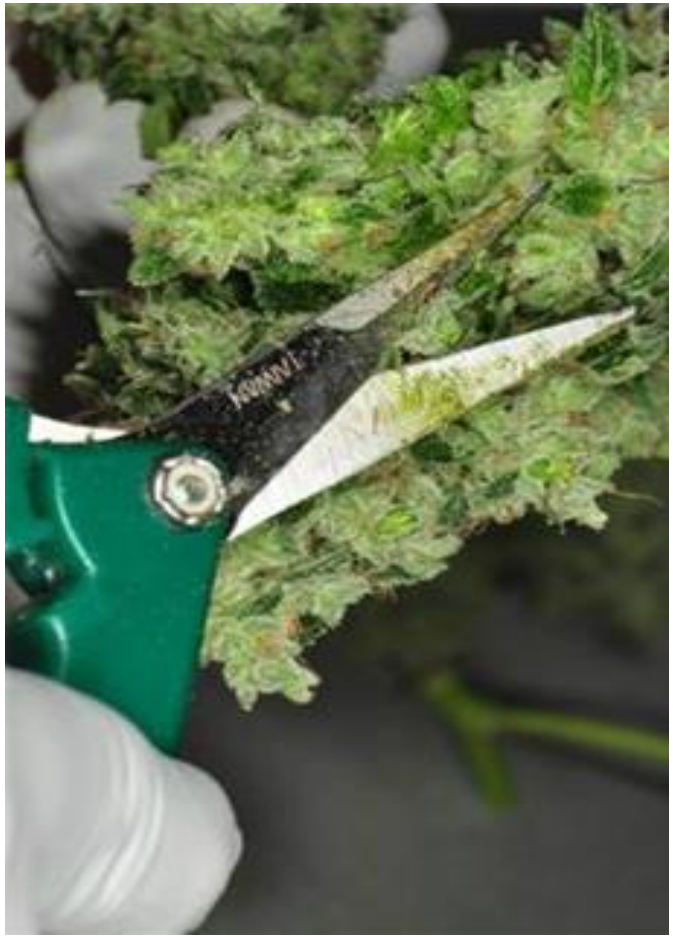
Extraction of cannabinoids

Food production

Distribution

Biological
Chemical
Physical
hazards





Traceability

Security

Training

Seed to Sale Tracking	California	Colorado	Massachusetts	Michigan	Oregon	Washington
						
Seed to Sale Tracking Vendors	METRC	METRC	BioTrackTHC	METRC	METRC	LEAF Data Systems

- *Food Safety Guidance – Cannabis infused products*
- *Cannabis 101- Glossary of terms*

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