Cannabinoid Safety and Regulation Act

Introduced by U.S. Senator Ron Wyden | 119th Congress

Section by section summary

Title I – Food and Drug Administration Regulation of Cannabinoid Products

Section 101–Food and Drug Administration (FDA) regulation of cannabinoid products.

General matters:

- Amends the Federal Food, Drug and Cosmetics Act to add "Chapter XI–Cannabinoid Products," to account for this law and related regulations.
- This legislation regulates hemp-derived cannabinoids and products that contain them, and the manufacturing, packaging, labeling, testing, and sale thereof.

Definitions:

- In short, a "**cannabinoid product**" is a natural (non-synthetic) product (including an inhalable, food, beverage or dietary supplement) made or derived from hemp, that contains some form, type or amount of cannabinoid(s) and/or tetrahydrocannabinol, that is intended for ingestion by, or use in or on the body of, human or animal.
    - A cannabinoid product is not an FDA-approved drug, a drug awaiting FDA approval, a biologic product, a medical device, a compound drug, an actively cultivated or growing cannabis plant, or hemp.
- A **cannabinoid** is any chemical in the cannabis plant that is unique to Cannabis sativa L., including acids, acetates, esters, ethers, derivatives, isomers, metabolites, precursors, or salts thereof, and any identical chemical or their analogues.
    - This includes but is not limited to tetrahydrocannabinols (THC), cannabinol (CBN), cannabidiol (CBD), cannabigerol (CBG), cannabichromene (CBC), hexahydrocannabinol (HHC), tetrahydrocannabiphorol (THC-P) tetrahydrocannabivarin (THC-V), tetrahydrocannabihexol (THC-H) cannabivarin (CBV), cannabidivarin (CBDV), cannabielsion (CBE), cannabicyclol (CBL), and cannabitriol (CBT).
- **Hemp** is as defined by the Agriculture Improvement Act of 2018 (7 U.S. Code §1639o): the plant Cannabis sativa L. and any part of such plant, including the seeds of such plant and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a THC concentration of not more than 0.3 percent, which is not intended for human consumption or application to the body of humans or animals.
- **Tetrahydrocannabinol (THC)** is the chemical found in or derived from cannabis in various forms, including delta-8, delta-9 and delta-10, as well as all isomers, acids, acetates, salts, esters, ethers, and derivatives thereof, including its precursor form, tetrahydrocannabinolic acid (THCa), any combination of these substances, and its hydrogenated forms (HHC and others).
- **Synthetic vs. semi-synthetic:** Wholly synthetic cannabinoid products are prohibited, but cannabinoid products that convert a cannabinoid extracted from a cannabis plant into a

different cannabinoid that is found in cannabis plants via a single chemical process are *semi*-synthetic, and are allowed so long as the products are free from any harmful constituents like chemical byproducts or residues.

- A **prohibited cannabinoid product** is:
    - Any product made with or from synthetically or artificially derived cannabinoids, including THC (this means made via chemical synthesis, modification or conversion, excluding decarboxylation and semi-synthetic cannabinoids);
    - Any product sold to children under the age of 21; and
    - Any product that is adulterated or misbranded under this Act, as follows.

Section 1102– Adulterated cannabinoid products:

- Cannabinoid products and their containers must not be contaminated, impure, or putrid, consistent with FDA requirements for foods, drugs and dietary supplements;
- Cannabinoid products may not be, and may not contain anything injurious to health;
- Cannabinoid products may only and must be produced in regulated and registered facilities that allow FDA inspection;
- Cannabinoid products must be, and may only be produced using regulated methods;
- These products must be tested for contamination and potency by state-licensed and accredited labs, and comply with FDA-established levels of safety for heavy metals, byproducts, and the like;
- Cannabinoid products may not contain unsafe food color additives; and
- Cannabinoid products may not contain more than the prescribed level of THC in each serving and package.

Section 1103– Misbranded cannabinoid products:

- Cannabinoid products may not have false or misleading labeling or advertising.
- Cannabinoid products, regardless of their form, must have a label that contains:
    - A prominent statement that says the product contains cannabinoids, and a internationally recognized symbol for cannabis, such as ASTM D8441 (left);
        - States may use one of two universal symbols to differentiate between intoxicating and non-intoxicating products at their discretion.
        - Further detailed in Section 1105(d) of this Act.
    - The business name and contact information for the manufacturer or distributor;
    - An accurate statement of the weight and amount of the product;
    - The amount (in milligrams) of THC in the product and in one serving/dose;
    - The content and amount (in milligrams) of all other cannabinoids in the the product and in one serving/dose;
    - Confirmation of testing analysis and information about where to view full test results;
    - Instructions for use, including how to divide into servings if applicable;
    - Directions for reporting adverse events;
    - Warnings against use by children and sensitive populations and a disclaimer that the product is not studied for safety or approved by the FDA; and

    - Disclosure of food allergens (like milk, wheat and soy).
- Cannabinoid products may not imitate or replicate products commonly associated with children, including commercially available candy, snacks or beverages, and may not have labels with cartoon or anthropomorphized figures.

Section 102 (a)-- Prohibited Acts:

Cannabinoid products are added to all existing FDA regulations regarding prohibited acts under Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §331). The Act also prohibits:

- The marketing, sale or distribution of a cannabinoid product to anyone under 21;
- Selling or distributing a cannabinoid product that contains alcohol, tobacco, and/or nicotine, or another substance with effects that could poorly interact with cannabinoids, as determined by the Secretary through rulemaking;
- Not clearly distinguishing between products for humans and animals;
- The failure of a manufacturer or distributor to notify the Attorney General of its knowledge of cannabinoid products used in illegal trade;
- Knowingly selling, distributing, or paying for any adulterated or misbranded cannabinoid products; and
- Altering, changing or destroying the label of a cannabinoid product when it's for sale.

Section 1104– Annual Registration and Product Categories:

- Annual registration is consistent with the Federal Food, Drug and Cosmetics Act's (FFDCA's) food facility registration system and processes.
- Registration is required by any domestic or foreign entity that manufactures, prepares, propagates, compounds, processes, packages, packs, imports, labels or holds cannabinoid products.
- Requires covered entities to register with the FDA biannually; registration affirms compliance with FDA rules and allows FDA to inspect the entity's facilities. There is no application process; it's an online web form. Must register within 30 days of initiating covered activity; the fee will be set by the Secretary, won't be over $500, but will index to inflation.
- Allows the FDA to suspend the registration of a facility or entity in instances of possible adverse outcomes, and provides for a notice, appeal and resolution process for suspended registrations.
- Requires registrants to submit product information to a product list; such list would need to be updated and provided to FDA before any new cannabinoid product could be introduced into commercial distribution (this is not pre-market approval, which is not required under this Act). The product list would need to be accompanied by all consumer information for the product including the label; such information would be kept confidential by FDA.

Section 1105– Additional FDA Regulation

- Sec. 1104(d)-- Allows FDA to issue a regulation to establish a Uniform Product Identification System for cannabinoid products.
- Sec. 1105(a)– Requires FDA to promulgate a rule regarding remote sales, promotion/marketing, and distribution of cannabinoid products in order to prevent youth access. Rule must require retailers of cannabinoid products to verify customers' age. Rule must be finalized within 18 months of enactment and remote sales will be allowed during promulgation of the rule.
- Sec. 1105(c)– Allows FDA to issue a regulation to establish a "nutrition facts"-like panel for cannabinoid product labels.
- Sec. 1105(e)-- Allows FDA to issue rules requiring tamper-evident and child safety packaging for cannabinoid products.
- Sec. 1105(f)-- Requires FDA to issue rules establishing good manufacturing processes for cannabinoid products within nine months of enactment.
- Sec. 1105(g)--Requires FDA to issue rules requiring testing of cannabinoid products within 18 months of enactment. The Good Testing Practice rule shall require a laboratory to be registered and accredited both in its state and federally, and use only analytically and statistically valid methods. Testing of cannabinoid products must confirm that the product is not contaminated with (pursuant to levels established by the Secretary):
    - Pesticides, chemical residues, residual solvents, including synthetic inputs used to produce semi-synthetic cannabinoid products;
    - Heavy metals, including arsenic, cadmium, lead and copper; and
    - Foreign matter both organic and inorganic, including mycotoxins.
    - The testing must also consist of a potency analysis for THC and other cannabinoids.
- Sec. 1105(h)--Allows food to be or contain cannabinoid products so long as the product meets all of the FFDCA's food standards as well as the cannabinoid product standards laid out in the Act.
- Sec. 1105(j)--Allows dietary supplements to be or contain cannabinoid products so long as the product meets all of the FFDCA's dietary supplement standards as well as the cannabinoid product standards laid out in the Act.

Section 1106– Product Standards

- Establishes a minimum age for the purchase of cannabis by requiring FDA to issue regulations to prevent the sale and distribution of cannabis products to individuals who are under the age of 21.
- Requires FDA issue regulations requiring that any imported cannabinoid products meet the same good manufacturing practice requirements, reliable testing requirements, and packaging and labeling requirements as well.
- Establishes THC serving sizes for four main product categories:
    1. Edible products (ingested orally) may only contain 5 milligrams of THC per serving and 50mg of THC per package.

2. Topical products (applied externally to the body) may only contain 5mg of THC per serving and 50mg of THC per package.
3. Beverage products (for drinking) may only contain 5mg of THC per serving and 10mg of THC per package.
4. Inhalable products (consumed via inhalation) may only contain 5mg of THC per serving and 50mg of THC per package.

- Requires FDA to adopt, by regulation, cannabis product standards that are appropriate for the protection of public health, and authorizes FDA to issue additional regulations to impose additional restrictions on the sale and distribution of cannabis products if it is determined that such restrictions are appropriate for the protection of public health.

Section 1107– Recall Authority

- Provides for the mandatory recall of a cannabis product if FDA determines that such product would cause serious, adverse health consequences or death.
- Outlines the requirements and procedures for a mandatory recall, including public notice.

Section 1108– Records and Reports on Cannabinoid Products

- Establishes recordkeeping requirements for manufacturers and importers of cannabis products.
- Such entities would also be required to provide information and make reports to FDA that are needed to protect public health and assure customers that their cannabis products are not adulterated or misbranded.

Section 1109– Prohibition on electronic cannabinoid product delivery systems

- Prohibits electronic cannabis product delivery systems from containing added natural or artificial flavors, except for natural terpenes.
- Prohibits electronic cannabinoid product delivery systems from containing more than 6% terpenes, in order to protect the public from inhaling terpenes at unsafe levels.

Section 1110– States' rights

- Nothing in this legislation preempts any Federal agency, any State (as defined to include Tribes and Territories), or any unit of a state from issuing any of their own laws or rules regarding cannabinoid products, including prohibition thereof, and imposition of taxes.
- This does not extend to the packaging or labeling of cannabinoid products, which must be consistent from state to state and abide by the requirements of this Act.
- States may not prohibit the transportation or shipment of cannabinoid products through the State.

Section 103–Regulation of cannabinoid beverages

- The Secretary of Agriculture, the FDA Commissioner, the Attorney General and the Director of the Alcohol and Tobacco Tax and Trade Bureau shall jointly publish a report recommending a federal regulatory framework for beverages that contain THC, which also addresses direct-to-consumer and distributor models of sale.

Title II—Public Health

Section 201– Public health surveillance and data collection.

- Invests an additional $200 million annually for five years for the Centers for Disease Control and Prevention (CDC) to increase public health research and data collection into cannabis use, including by funding evidence-based drug use prevention activities.

Section 202– Awards to prevent underage cannabis use.

- Invests $25 million annually for five years for the Substance Abuse and Mental Health Administration (SAMHSA) to fund grants to states and nonprofits for projects to prevent and reduce underage use of cannabis.

Title III— Cannabis-Impaired Driving Prevention

Section 302– Cannabis-Impaired Driving Research

- Directs the Departments of Transportation and Health and Human Services to collect data on cannabis-impaired driving, including through a national roadside survey.

Section 303-304– Cannabis-impaired driving prevention programs.

- Requires DOT to collect data, raise awareness, and enforce against impaired driving, and enhance use of state data linkage systems with respect to impaired driving.
- Asks state departments of transportation to collect data, raise awareness, and enforce against impaired driving, and enhance use of state data linkage systems with respect to impaired driving.
- Provides $40 million a year for five years to carry these grant programs out.

Section 305-306– National cannabis impairment standard.

- Funds research to enable the development of an impairment standard for driving under the influence of cannabis.
- Provides $30 million a year for five years to carry out this Title.