

Principles for Federal Oversight of the Adult-use Cannabis Supply Chain



About Wine & Spirits Wholesalers of America

WSWA is the national trade association representing the distribution tier of the wine and spirits industry, dedicated to advancing the interests and independence of distributors and brokers of wine and spirits. Founded in 1943, WSWA has more than 380 member companies in 50 states and the District of Columbia, and its members distribute more than 80 percent of all wine and spirits sold at wholesale in the United States.



Table of Contents

| 1. | A History of Success: Lessons From Smart Alcohol Regulation4 |
|------|---|
| 11. | The Four Principles of Safe and Responsible Adult-use Cannabis Regulation 6 |
| III. | Federal Permitting of Cannabis Producers, Importers, Testing Facilities and Distributors8 |
| IV. | The Approval and Regulation of Cannabis Products |
| V. | Efficient and Effective Collection of Federal Excise Tax |
| VI. | Ensuring Public Safety 13 |
| VII. | Why Do America's Wine and Spirits Wholesalers Care?15 |



I. A History of Success: Lessons From Smart Alcohol Regulation

For nearly 90 years, the U.S. wine, beer, and spirits marketplace has been a global leader in product safety, industry innovation, and consumer choice. This result is not coincidental; rather, it follows from a shared state-federal regulatory structure that has placed oversight of permitting, product approval, tax collection, and intraindustry conduct with the federal government, while allowing states to establish independent systems that supplement these provisions to address local needs and priorities. It is this system that laid the foundation for talented brewers, winemakers, distillers, importers, distributors, and retailers to build the industry we enjoy today.

One of the most remarkable aspects of this system is its adaptability. The underlying regulations in place today are largely unchanged from nearly a century ago, yet innovation abounds — in the form of new products, packaging, retail business models, home delivery, and more. For instance, according to the U.S. Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB), the number of applications received for new alcohol beverage labels has increased 50 percent in just the last decade and there has been roughly a 90 percent increase in the number of licensed distilleries (FY15-19).

This growth shows the adaptability and time-tested resilience of the federal alcohol model of **permitting** — whereby the TTB licenses producers, importers, and distributors to perform those functions; **product testing** — whereby all products entering commerce must have a federally approved label and meet applicable markettesting requirements; **taxation** — whereby federally permitted producers or importers must remit federal excise tax; and **public safety** — whereby embracing a comprehensive, anti-impaired driving strategy has led to significant decreases in alcohol-related accidents and fatalities

Increased Percentages since 2010

+50%

Number of applications received for new alcohol beverage labels has increased 50 percent in just the last decade

U.S. Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB)

+90%

Increased in the number of licensed distilleries

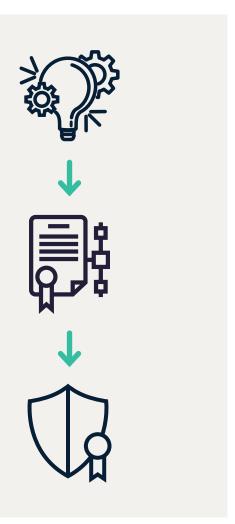
U.S. Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB)



All of these benefits should be the goal of any proposal to legalize and regulate adult-use cannabis. The core features of federal alcohol regulation should be the model upon which to build a federal cannabis regulatory system.

In this paper, we outline these four primary principles and how they can help ensure the safe and efficient transition from the isolated intrastate cannabis regulatory systems of today to the interstate system that will follow federal legalization. We specifically highlight the role of permitting in this system as it promotes the highest level of industry accountability—since running a business under such a regulatory regime depends on having a permit.

It is important to note that nothing in this proposal prevents states from enacting stronger measures within their borders, nor does it require any state that has already legalized cannabis to alter its existing regulatory structure. By focusing on the regulation of production, distribution, and interstate transport of cannabis, our proposal promotes federal interests while maintaining flexibility of each state to respond to the wishes of its citizens.





These four primary principles can help ensure the safe and efficient transition from the isolated intrastate cannabis regulatory systems of today to the interstate system that will follow federal legalization.



II.The Four Principles of Safe and Responsible Adult-use Cannabis Regulation

Below, we introduce four principles for federal adult-use cannabis regulation that build on the successes of the federal beverage alcohol regulatory model.

These are:

1.

The federal permitting of cannabis producers, importers, testing facilities and distributors;

2.

The approval and regulation of cannabis products;

3.

The efficient and effective collection of federal excise tax; and



Effective measures to ensure public safety



These are explored in more detail on the following pages, but it is important to understand that these principles work together to ensure:









Only parties with the appropriate federal permit:

- **Produce** cannabis or cannabis-derived products
- · Import cannabis or cannabis-derived products
- · Test cannabis or cannabis-derived products for potency and purity
- · Distribute cannabis or cannabis-derived products.

Only products that meet the required federal standards enter the marketplace:

- · Properly labeled and formulated
- · Packaged in approved sizes, weights and volumes
- · Meet **ongoing** testing requirements for potency and purity

Efficient federal excise taxation:

• **Remitted** by producer or importer licensees to the TTB.

Public safety:

 Prioritized through continuing research to develop impairment standards and detection technology and procedures.

All of the above requirements are based on elements of the federal alcohol model. With decades of experience regulating alcohol, the Alcohol and Tobacco Tax and Trade Bureau (TTB) is uniquely qualified to assume oversight of adult-use cannabis. Year after year, the TTB acts as one of the most efficient tax collecting entities in the federal government and has a strong record of managing the permitting and enforcement provisions of federal law. Under the TTB's watch, the industry has had an unparalleled safety record, while also experiencing the growth of both the number of products and producers in the marketplace.

The TTB handles the following functions for beverage alcohol that can be adapted to cannabis:

- Permitting of alcohol producers, importers and distributors.
- Review and approval of product formulas and alcohol labels.
- Excise tax collection from domestic manufacturers and importers.
- Enforcement of trade practice and advertising regulations that create a fair and level playing field for the industry.
- Ongoing market compliance monitoring to ensure (TTB) compliance with labeling, advertising and trade practice requirements.



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III. Permitting of Cannabis Producers, Importers, Testing Facilities, and Distributors

Permits are at the core of the U.S. alcohol regulatory system as they:

- Ensure entrants to the industry meet applicable requirements before engaging in the business.
- Provide the public with transparency into the industry through public permittee registries.
- Promote permittee accountability, since permits are revocable.

The TTB alcohol permit process can be readily adapted to adult-use cannabis by creating a federal basic permit that all cannabis producers, importers, testing facilities and distributors must obtain. The key provisions of this system are highlighted below.

What is it? A federal basic permit (FBP) is a permit issued by the TTB that authorizes a company to engage in specified commercial activities involving cannabis at a particular location.

Permit classes:

- **Producer** cultivation, processing and product manufacture.
- Importer importation of cannabis from a foreign country for sale into domestic commerce.
- Product Testing subjecting products to analysis for residual pesticides and purity.
- Distribution packing, storing and transporting products between producer or testing permittees and retailers.

Who is eligible?

- A person who has not committed a felony (other than non-violent cannabis-related offenses that occurred prior to federal legalization/descheduling) in the five years prior to application.
- A company that is likely to commence operation within a reasonable period and maintain such operations in conformity with federal law, and will not be conducting business in violation of state law.

What activities does a producer FBP allow?

A producer FBP allows the holder to engage in the business of cannabis cultivation or manufacturing and to receive, sell, offer or deliver for sale, contract to sell, or ship in interstate or foreign commerce, directly or indirectly or through an affiliate, the cultivated or manufactured cannabis products. Only the holder of a producer FBP may cultivate cannabis for sale. In addition to an FBP, a producer must post a bond as established in TTB regulation to cover the producer's excise tax liability on cannabis produced or received by the producer.

May a producer FBP holder also hold a distributor FBP? Yes. There is no federal prohibition on a person or company holding both a producer and distributor FBP.

May a producer sell cannabis to a consumer? A producer can sell cannabis to a consumer in the state in which the cannabis is manufactured if permitted by state law. Sales and shipments from producers to consumers across state lines are not permitted.



What activities does an importer FBP allow?

An importer FBP allows the holder to import cannabis into the U.S. from another country where it is federally legal and sell cannabis to any federally licensed producer or distributor. An importer is responsible for complying with all the same product regulations as a domestic producer (label approval formula, etc.) and must remit federal excise tax to the TTB when the product is removed from the importer's premise for sale into commerce. An importer FBP is compatible with both producer and distributor FBPs — that is, a single entity could hold all three.

Who can an importer sell to? A federally permitted importer may sell to any FBP producer or distributor. The importer FBP has the same sale privileges as an FBP producer.

What activities does a product testing FBP allow?

A product testing permit allows the holder to test producers' or importers' cannabis products to determine potency and ensure compliance with residual pesticide requirements. This testing is distinct from product approval testing done by the TTB before a product can enter the marketplace for the first time (formula and label approval).

Who may hold a product testing FBP? Similar to state law, cannabis producers, importers, and retailers are prohibited from holding a product testing FBP.

What activities does a distributor FBP allow?

A distributor FBP allows the holder to engage in the business of purchasing cannabis for resale (from an FBP producer or another FBP distributor) and receive, sell, offer, or deliver for sale, contract to sell, or ship in interstate or foreign commerce, directly or indirectly or through an affiliate, the products purchased for resale.

- **Example:** Only the holder of a federal basic distributor permit may purchase cannabis from a producer in State A for resale (to another distributor or retailer) in State B
- **Example:** A producer operating in State A may obtain a distributor FBP in State B in order to sell its products to a retailer in that state.

May a distributor sell cannabis to a consumer? A distributor can sell cannabis to a consumer in the state in which the cannabis is manufactured if permitted by state law. Sales and shipments from distributors to consumers across state lines are not permitted.

What activities doesn't a basic permit allow? Only activities outlined in the permit's authorizing regulations are allowed with respect to cannabis. Holding a federal basic permit does not prohibit the permittee from engaging in other licensed/permitted activities at the state or federal level.

Who issues and regulates the permit/permit holder? The TTB would have permitting and regulatory responsibility for all federal basic permit holders. The TTB also would be responsible for the collection of federal excise tax (discussed below).

Who can transport products across state lines? Only a federally permitted producer, importer, or distributor may contract with a federally licensed motor carrier for interstate transport between producers, importers, and distributors. In addition, all transport of products to retailers must be conducted by a federally permitted distributor.

What about *retail* sales? Cannabis retailers would be licensed at the state level. Sales to consumers and other retailers across state lines are prohibited.



IV. The Approval and Regulation of Cannabis Products

Similar to industry member **permitting,** a robust process for **approving** new products (labels and formulas) is central to the beverage alcohol system and can be replicated in the cannabis context.

Additionally, state cannabis systems today employ a quality and safety assurance mechanism through **ongoing product testing**, which should be included in a federal cannabis system. These provisions ensure products enter the marketplace only after meeting a system of approvals that make the U.S. system the most safe and reliable in the world.

What products are regulated? All cannabis that will be sold to a consumer.

Does an FBP authorize the holder to cultivate or distribute hemp or CBD products? So long as the activity is not incompatible with state law, the FBP does not restrict the holder from engaging in other lawful activities.

Who regulates the product? The TTB has regulatory oversight of all cannabis products including flower, edibles, oils, tinctures, and all products that contain THC in concentrations exceeding the USDA definition of "hemp" (currently not more than 0.3 percent).



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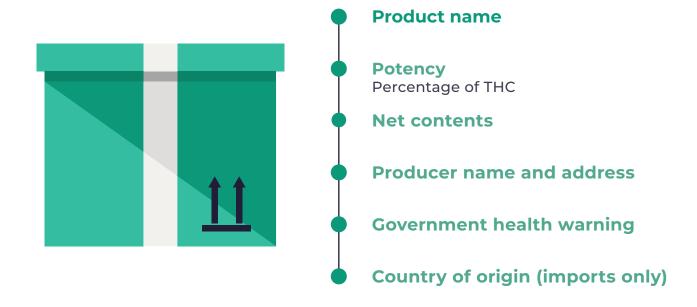
How are products regulated by the TTB?

Pre-market approval: Prior to introduction into commerce, a cannabis product containing
non-cannabis ingredients must submit a formula to the TTB for approval. A formula approval is required
before a label may be issued for such products.



- **Product registration and label approval:** All products that a producer or distributor intends to sell or ship, or deliver for sale or shipment, or otherwise introduce into commerce must have an approved label (Certificate of Label Approval, or COLA) issued by the TTB. A producer may not sell a product to anyone but another producer unless the product bears an approved COLA. Similarly, a distributor is responsible for ensuring that all products it purchases from producers are properly labeled.

Mandatory elements of a label include:



- **Proof of laboratory approval:** Producers must obtain proof of a satisfactory lab test for potency and residual pesticides from an FBP testing permit holder for all cannabis prior to its sale into commerce. These results must be retained by the producer for a minimum of three years and a copy provided to all purchasing distributors, who must retain such approvals for a minimum of three years. Laboratory test protocols (including testing frequency) and standards are to be established via TTB regulation.
- Units of sale: Potency is measured in milligrams of THC per serving. Limits should be established by regulation as to the maximum quantity sold per package, taking into account product type (flower, edible, oil, beverage, etc.). At a minimum, upper and lower quantities should be established. Beverage alcohol uses "standards of fill," which specify the volumes of alcohol that may be sold. A similar approach could be udeveloped for cannabis.



V. Efficient and Effective Collection of Federal Excise Tax

Federal excise tax (FET) is imposed on wine and distilled spirits based on the percentage alcohol by volume (for wine) and proof gallons (for distilled spirits). In both cases, the underlying concept is the same — higher taxes are imposed on higher-potency products. This serves an important public policy goal, preventing the promotion of low-cost, high-potency products that would be incentivized under a "percentage of sales price" taxation approach. FET is collected by the TTB on domestically manufactured alcohol when it leaves the manufacturer's bonded premises for sale and the same model should be employed for adult-use cannabis

Excise tax rate: Recreational cannabis is assessed a federal excise tax when it leaves the producer's or importer's bonded premises for sale. The rate is based on the potency of the product, similar to the proof gallon concept used to determine the FET for distilled spirits.

Collection point: Excise tax must be remitted by the producer when the product leaves the producer's licensed premises or by the importer when the product leaves the importer's premises. Sales between producers do not incur tax liability until sale from the last producer to a distributor (or producer to retailer, if state law allows).

Tax remittance: Taxes are payable to the TTB on a semimonthly basis.

State excise taxes: State excise taxes are paid in accordance with existing state law. However, with the introduction of sales across state lines, when a finished cannabis product is sold by a producer to a distributor in another state, the distributor is responsible for remitting all state excise taxes that would be due from either a producer or distributor on products manufactured in state. In this way, the federal regulations are supporting state tax collection.



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VI. Ensuring Public Safety

In 2018, drinking-related fatalities decreased by 3.6 percent, accounting for 29 percent of overall traffic fatalities — the lowest percentage since 1982, when the National Highway Traffic Safety Administration (NHTSA) began reporting data on such events. While drunk driving crashes and fatalities are at near-record low levels in America, there has been a steady rise in drug-impaired, or "drugged-driving," incidents and fatalities.

The rates of drug-impaired driving are an increasing threat to public health and safety, particularly in states that have adopted measures to legalize recreational cannabis use, as it remains the most frequently detected drug in the systems of fatally injured and arrested impaired drivers.

The 2013–2014 National Roadside Survey of Alcohol and Drug Use found that the percentage of weekend nighttime drivers who tested positive for marijuana grew by nearly 50 percent from 2007. According to the 2016 Governors Highway Safety Association (GHSA) report, 44 percent of fatally injured drivers with known results tested positive for drugs, up from 28 percent in 2006. More than half of these drivers had marijuana, opioids, or a combination of the two in their systems.

The federal government should fight impaired driving in all forms by embracing a comprehensive, anti-impaired driving strategy.

-3.6%

Drinking-related fatalities accounting for 29 percent of overall traffic fatalities In 2018— the lowest percentage since 1982

National Highway Traffic Safety Administration (NHTSA)

+50%

Growth of weekend nighttime drivers was found by National Roadside Survey of Alcohol and Drug Use in 2013–2014 from 2007.

National Road Survey of Alcohol and Drug Use

44%

of fatally injured drivers with known results tested positive for drugs, up from 28 percent in 2006. More than half of these drivers had marijuana, opioids, or a combination of the two in their systems

According to the 2016 Governors Highway Safety Association (GHSA) report



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BAC equivalency: Federal law enforcement agencies, in conjunction with state agencies, should develop a reliable standard for all types of impaired driving, similar to blood alcohol concentration (BAC). The NHTSA should coordinate research efforts with states and other partners to ensure that all stakeholders have input into the process.

At the same time, recognizing that developing a standard measurement of cannabis impairment remains unlikely in the near term, federal regulators should prioritize the study and development of a standardized field sobriety test (SFST) to detect cannabis impairment.

Law enforcement training and toxicology lab funding: Law enforcement officers and prosecutors should continue to be trained in the detection and adjudication of drug-impaired and multi-substance impaired drivers and enhanced resources should be allocated to enable toxicology labs to better process test results in a timelier manner.

Legislation and regulatory action is needed to direct the NHTSA to continue funding training efforts with law enforcement and prosecutors, such as Drug Recognition Experts (DREs) and Advanced Roadside Impaired Driving Enforcement (ARIDE) training and expand efforts to fund toxicology labs, particularly in states that have adopted recreational and medicinal marijuana laws. The NHTSA should also provide states with flexibility to use impaired driving countermeasures grants for these purposes.

Drug-impaired driving detection technology: Legislators and regulators should continue to promote the development of technologies to detect the presence of drugs in the systems of suspected impaired drivers. Such technologies are especially valuable to law enforcement officers as another tool to strengthen drug-impaired driving investigations and assist in determining whether a case should be referred to a Drug Recognition Expert (DRE) to perform an evaluation. These technologies, such as oral fluid testing, have a demonstrated the ability to detect a multitude of drugs rapidly and accurately, and have been successfully utilized by law enforcement to remove impaired drivers from roadways, thereby saving lives.

In addition, legislators and regulators should direct the NHTSA to coordinate with other federal agencies to create an inventory of available new methods for detecting recent drug use and provide details to Congress on the technologies available to identify drugs in the systems of suspected impaired drivers, while also recognizing challenges to increased utilization of these technologies. Congress should also direct the NHTSA to work with prosecutors, law enforcement, toxicologists, and other relevant stakeholders to develop best practices for the implementation and use of oral fluid testing technology.



VII. Why Do America's Wine and Spirits Wholesalers Care?

The transition from Prohibition to legal status for alcohol has been an American success story. Since the enactment of the 21st Amendment, a safe and economically vibrant marketplace has developed — one that serves the dual needs of regulators and consumers. While individual regulations have been modified over time, the basic federal regulatory structure of permitting and tax collection has stood the test of time. As policymakers consider the future of adult-use cannabis, we believe it is important to share the learnings of our industry. America's wine and spirits wholesalers are a proud part of this system and believe that the principles outlined here can be extended to a national adult-use cannabis system.

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WINE & SPIRITS WHOLESALERS OF AMERICA