

# Cannabis legalization

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# Factsheet: Cannabis legalization

## Why should recreational cannabis be legalized?

### Status quo



- **2.5 % of the world population uses cannabis annually** (WHO, 2020)



- **24.7 million cannabis users in Europe** (EMCDDA, 2019a)



- **Consumption in Germany: 400 tons of cannabis per year** (Haucap & Knoke, 2021)

- **Increase in consumption is likely** (Smart, 2019)



- Cannabis from illicit markets is often mixed and contaminated with dangerous substances, such as synthetic cannabinoids, lead and/or hairspray (ZDFheute, 2021)



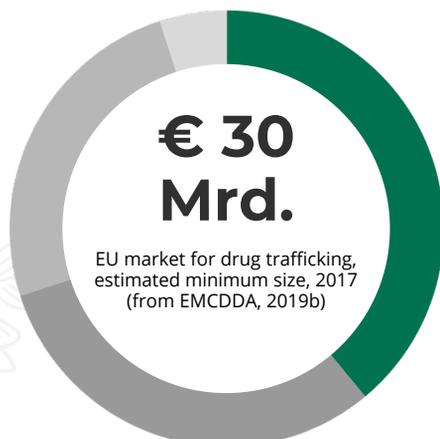
- In 2015, 2.3 tons of synthetic cannabinoids were seized in Europe, and this trend is only rising (EMCDDA, 2017)

#### ● Cannabis

#### ● Kokain

#### ● Heroin

#### ● Andere



- Cannabis trafficking accounts for the majority of total turnover attributed to illicit drug markets (Mejía & Csete, 2016)
- Illicit market traffickers' revenues were estimated at 11.6 billion euros in Europe in 2017 (EMCDDA, 2019b)
- The money supports organized crime whilst generating no revenue for the state (Stöver & Plenert, 2013)

## Prohibition has failed - only the illegal drug markets profit

### Aims of the controlled supply of cannabis to adults

- Protection of children and young people
- Health protection of consumers
- Quality assurance of the products (Deutscher Bundestag, 2022)

### Possible further goals of a cannabis policy (Rolles & Murkin, 2016)

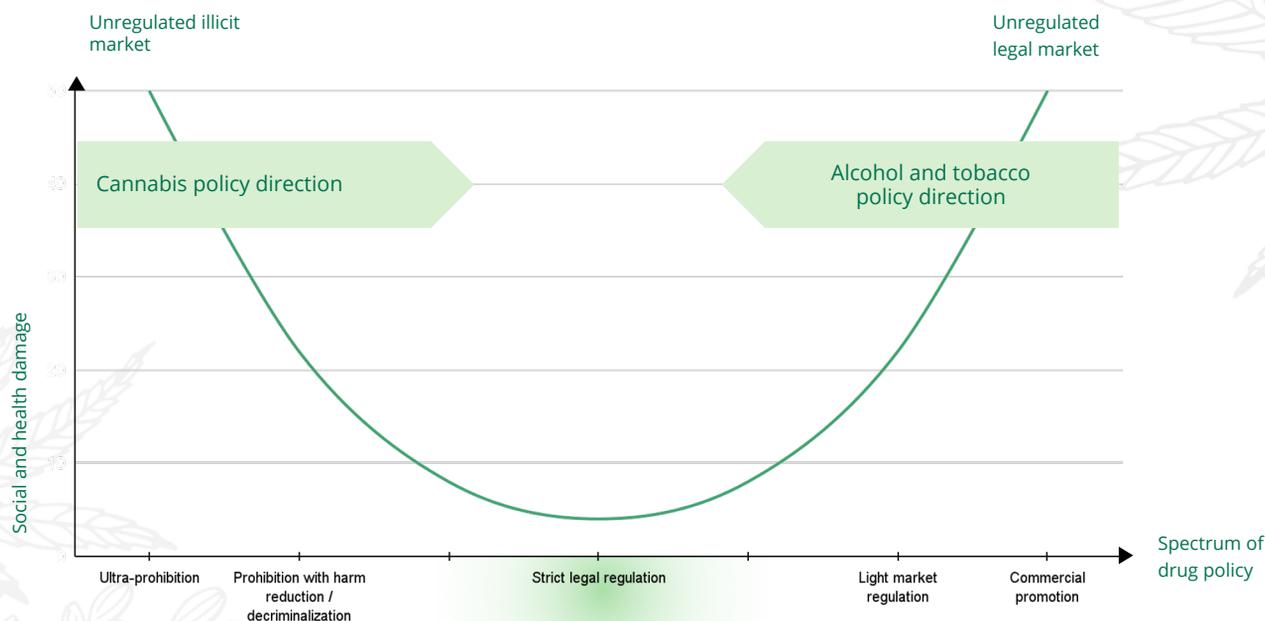
- Protection and improvement of public health
- Reduction of drug-related crime
- Curbing the illicit market
- Savings for the judiciary and police through fewer prosecutions
- Collection of taxes and fees
- Protection of human rights

## Coalition agreement is the first step toward a progressive, modern drug policy

## Why should recreational cannabis be legalized?

### What could the regulated dispensing of Cannabis look like?

- There are a wide range of legal and policy measures regulating production, distribution and dispensing
- Unregulated markets are at both ends of the spectrum
- Regulated market models in the middle of the spectrum are optimal for social and health protection
- Combinations of models are possible (Rolles & Murkin, 2016)



Paradox of prohibition (according to Rolles & Murkin, 2016)

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# Factsheet: Cannabis legalization

## Displacement of the illicit market

### Benefits of combating the illicit market (Meadows, 2019)



#### Improvement of public safety

- Reduction of criminal activities, "gang wars"
- Reduction of income sources and the resulting power for players in the illicit market



#### Improving public health

- Reducing dangerous and unregulated products
- Testing and quality assurance of products

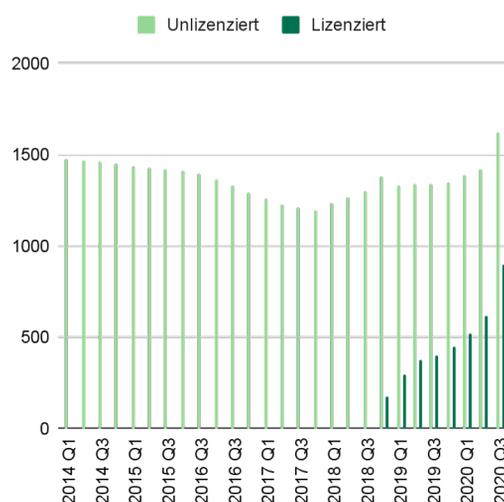


#### Improving the economy

- Tax revenue for social projects
- Job opportunities

### Possible reasons why consumers do not switch from the illicit market to legal products (Meadows, 2019)

- Lower price
  - Tax free
  - No royalties, compliance costs, fair pay for workers
- Quality
  - "Craft" cannabis from experienced growers
  - No ionising irradiation of the product
- Uncomplicated
  - No restrictions on potency and quantity
  - Home delivery of illicit market products
- Variety of products
- Familiarity (close relationship with the "dealer")
- Discreteness and anonymity
- Underage
- Thrill seeking



Household expenditure on cannabis products for non-medical use, Canada 2014-2020 (UNODC, 2021)

### Measures to sustainably combat the illicit market

- Allow import of products to meet market needs
- Low tax rate and prices at "illicit market" level
- High quality and variety of products
- No limits on THC content and maximum dispensing quantity
- Allow home grow and cannabis social clubs
- Allow online distribution
- Establish sales outlets throughout the country
- Allow advertising / information to adults
- Allow branding of products

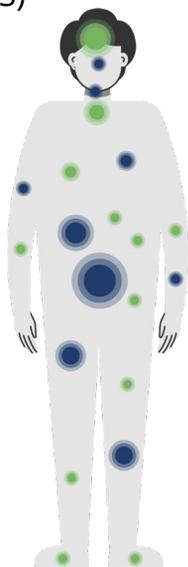
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# Factsheet: Cannabis legalization

## Cannabis use by adults

### THC acts by binding to the receptors in the **Endocannabinoid-System** (ECS)



- The ECS is part of the human nervous system
- It is composed of cannabinoid receptors (CB1 and CB2) and endocannabinoids and enzymes (Lu & MacKie, 2016)
- The ECS is involved in vital processes such as (Fraguas-Sánchez & Torres-Suárez, 2018):
  - Energy balance
  - Appetite stimulation
  - Blood pressure
  - Pain modulation
  - Embryogenesis
  - Control of nausea and vomiting
  - Memory
  - Digestion
  - Learning
  - Immune response

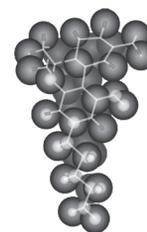
- THC can partially bind to receptors (higher affinity for CB1) through its analog, three-dimensional structure to the endocannabinoid anandamide ("Ananda" Sanskrit for "bliss") (Fraguas-Sánchez & Torres-Suárez, 2018)
- Through this, THC has the ability to affect pain, spasticity, sedation, appetite and mood (Russo, 2011)
- Ongoing research is constantly expanding the constituents and functions of the ECS (such as adding more metabolizing enzymes and receptors)

Chemical substance in the brain



Anandamide

Drug



THC

Structure of THC compared to anandamide (after NIDA, 2020)

### Why cannabis is used

Cannabis in "recreational use" can have an influence on, among other things:

- Relaxation
- Pain relief
- Mood
- Sociability
- Appetite
- Perceptions of color, time and space (de Melo Reis et al., 2021)

## Cannabis use by adults

### Short-term side effects due to imprecise action of THC in the ECS

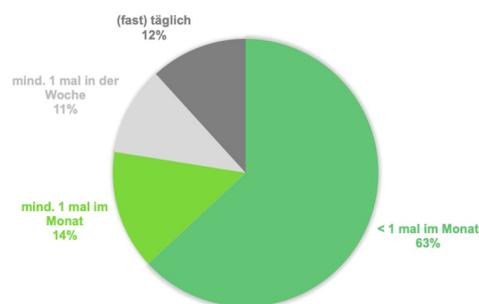
Possible short-term side effects of THC:

- Effect may be desirable in one case and undesirable in another, e.g., sedation, increased appetite, muscle relaxation
- Possible acute side effects mainly affect the psyche (euphoria, anxiety, fatigue, drowsiness, confusion) and psychomotor function (decreased psychomotor performance and traffic-related performance), as well as the heart and circulation (tachycardia, drop in blood pressure, dizziness, syncope) (Grotenhermen & Häussermann, 2017)
- For medicinal cannabis, THC side effects have been classified as mild to moderate (Fraguas-Sánchez & Torres-Suárez, 2018)

### Intense cannabis use can cause long-term side effects

Repeated and prolonged cannabis use can:

- lead to cannabis use disorders (CUD) and dependence, which affects approximately ten percent of regular users (Rup et al., 2021)
- lead to tolerance development and reversible forms of cognitive impairment, particularly of attention and memory (Hall et al., 2001)
- be associated with increased risk of mental disorders when predisposed (Lev-Ran et al., 2014; Hines et al. 2020; National Academies, 2017)
- be associated with adverse respiratory effects when smoked (National Academies, 2017)
- significantly increase the risk of adverse effects with higher frequency of use and higher THC content (Anderson et al., 2019)
- but have no adverse effects on blood, liver, kidney, or hormone levels (Ware et al., 2015)



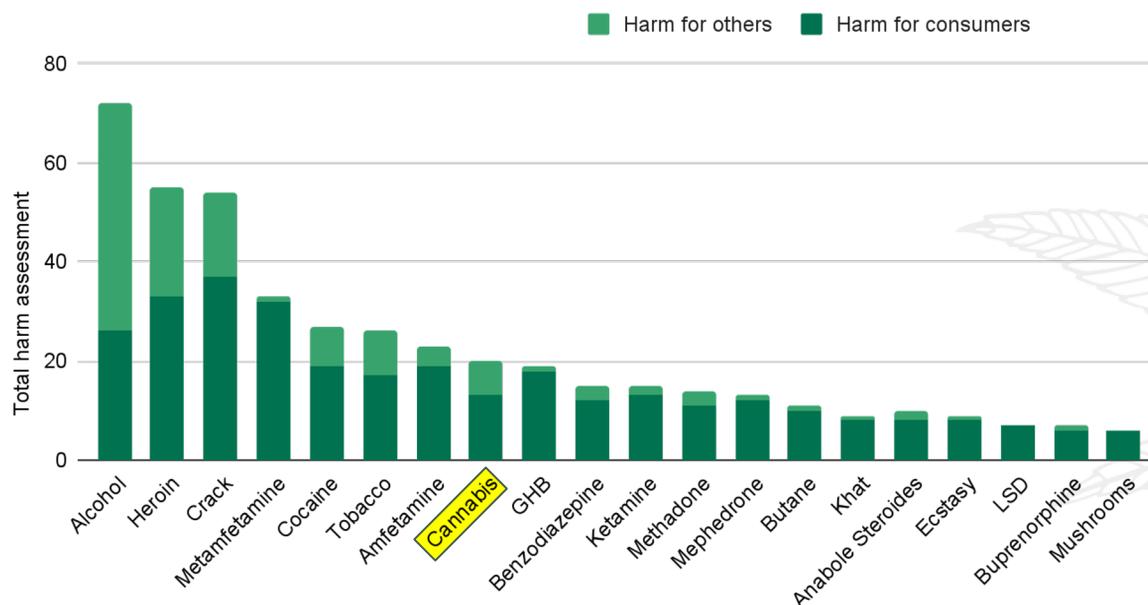
Consumption frequencies of the 12-month users (ESA, 2018)

### Certain groups of people should not use cannabis

Cannabis should not be used (Likar et al., 2017):

- if there is a personal or family history of psychosis or schizophrenia
- in the presence of unstable coronary artery disease
- during pregnancy or lactation
- by minors

## Cannabis use by adults



Drug-related harms in the United Kingdom (Nutt et al., 2010)

The potential for harm to users and others is lower for cannabis than for many other stimulants and drugs (Nutt et al., 2010)

## Alcohol is more harmful than cannabis

Table: Comparison of health harms of cannabis and alcohol (nach Sellman, 2020)

\*Evidence that ethanol is more harmful than Delta9-THC.

\*\*Good evidence that ethanol is significantly more harmful than Delta9-THC.

	Cannabis (Delta9-THC)	Alcohol (Ethanol)
Risk of death from overdose	almost zero	relatively high**
Aggressiveness during intoxication	low	moderate/high**
Anxiety during intoxication	moderate	nearly zero
Risk of damage when driving while intoxicated	moderate/high	high*
Irritability during withdrawal	moderate	moderate
Risk of death during severe withdrawal	nearly zero	relatively high**
Brain damage during chronic heavy use	possible	definitely**
Risk of fetal brain damage	probably low	very high**
Risk of liver and other organ damage	low	high**
Risk of developing addiction	moderate	moderate
Triggering of psychotic states	yes, but very rarely	yes, but rarely
Causing severe depression	possible	definitely*
Causing cancer	no evidence for THC, but possible when smoking as a form of consumption	definitely carcinogenic**

## Cannabis use by adults

### Lower-risk, self-determined, non-medical cannabis use

#### Example Canada: "Guidelines for lower-risk cannabis use" (adapted from Fischer et al., 2017)

1. The only way to avoid the risks is to not use cannabis
2. The earlier use is initiated, the more severe the negative effects are likely to be
3. The higher the THC content of the product, the higher the risk for mental health problems
4. Do not consume synthetic cannabinoids
5. Prefer vaporizers or oral products to smoking
6. When smoking, do not inhale deeply and hold your breath (this increases the absorption of toxins)
7. Limit cannabis use as much as possible to minimize risks (e.g. 1x per week)
8. Do not drive a vehicle or operate machinery for at least six hours after consumption
9. Persons with predispositions to psychotic disorders as well as pregnant women should refrain from consumption altogether due to the precautionary principle
10. Do not use cannabis at the same time as alcohol or other drugs
11. The combination of the above-mentioned points increases the risk negative health consequences
12. When using cannabis, be aware of the risks and side effects, which depend on the characteristics of the user, consumption patterns and product properties

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## Youth protection

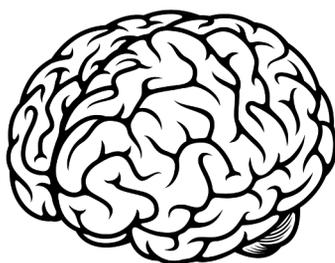
### Frequent cannabis use may lead to cognitive impairment in adolescents

Reduction of gray matter in the brain, as THC can disrupt the critical phase of brain development (Battistella et al., 2014)

Negative impact on areas of the prefrontal cortex that control important cognitive processes

Changes in brain function that negatively impact academic, occupational, and social performance

Impairment of short-term memory and reduction in concentration, attention span and problem-solving abilities (Volkow et al., 2014, Chen et al., 2009, Zalesky et al., 2012, Meier et al., 2012, Maggs et al., 2015)



Higher rates of psychosis in adolescent consumers with a predisposition to schizophrenia (Moore et al., 2007)

Higher likelihood of cannabis dependence in adulthood (Schepis et al., 2008)

Unlike adults, adolescent use of cannabis is associated with more concurrent and long-term consequences on cognitive functioning than alcohol (Nutt et al., 2010, Morin et al., 2019)

### How does cannabis legalization affect youth use?

#### International experience:

- There is little evidence that cannabis legalization promotes its use amongst adolescents (Anderson et al., 2019, Coley et al., 2021, Montgomery et al., 2022)
- Following the introduction of legal cannabis dispensaries in Colorado, USA, there was no significant impact on adolescent cannabis use; frequent cannabis use and use on school grounds actually decreased (Brooks-Russell et al., 2017)
- The pandemic also did not lead to increased cannabis use amongst adolescents in Canada (Leatherdale et al., 2021)
- Education and the reduction of stigma around cannabis use may help address mental health issues related to cannabis use after legalization (Wadsworth et al., 2020)

**There is little evidence suggesting an increase in cannabis use amongst adolescents in North America since its legalisation**

## Youth protection

### Challenges in ensuring the protection of minors

- Determination of an optimal age limit (too high → continuation of illicit market; too low → incentive to consume)
- Implementing evidence-based prevention and harm reduction programs
- Determination of suitable public spaces for consumption (Rolles & Murkin, 2016)

### What measures have other countries taken to protect young people?



- Austria and Switzerland: CanReduce online self-help program for cannabis-using youth <https://www.canreduce.at>

- Switzerland and Germany: Ready4life social skills app for adolescents <http://www.ready4life.info>



- Denver (USA): Cannabis education campaign for youth "High Costs" <https://www.thehighcosts.com/about/>

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# Factsheet: Cannabis legalization

## The myth of the "gateway drug"

The **"gateway drug hypothesis"** was popular in 1970s/80s and was disseminated under the administration of U.S. President Raegan (Kleinig, 2015)

Use of "soft drugs" (e.g. cannabis) leads to use of "hard drugs" (e.g. cocaine) and serious drug addiction (Government of Canada, 2016)

The theory has already been refuted several times in scientific journals (Drug Policy Alliance, 2017)



Cannabis is indeed used by individuals who also use hard drugs (Drug Policy Alliance, 2017),

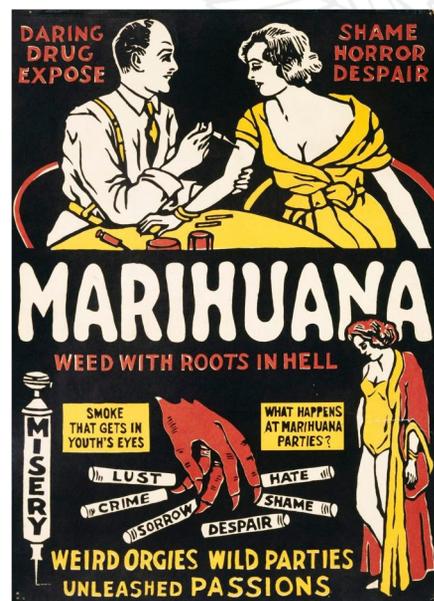
**However, correlation does not equal causation**

(Drug Policy Alliance, 2017)

Users' contact to harder drugs, e.g. the "dealer", exists due to the illegality of cannabis

**Most common legal "gateway drugs" are alcohol and nicotine**, which are usually used before reaching the age of majority and before the first use of cannabis (Drug Policy Alliance, 2017)

Drug abuse, dependence and addiction depend on **complex interactions** between various individual/predisposing factors and environmental factors (e.g. peer pressure, family influence, availability of drugs, opportunities to use drugs) (Government of Canada, 2016)



Billboard advertising the anti-marijuana film: The Weed with Roots in Hell 1936 (Forbes, 2021)

Drug users tend to have underlying tendencies towards drug frenzy that are not specific to a particular drug (RAND Drug Policy Research Center, 2002; Tarter et al. 2006)

**Cannabis is more of an "end drug" or "exit drug"**, because the vast majority of cannabis users do not switch to other illicit drugs. Moreover, cannabis can help to reduce/stop the use of more harmful drugs because it relieves withdrawal symptoms (Center for Behavioral Health Statistics and Quality, 2015; Drug Policy Alliance, 2017)

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# Factsheet: Cannabis legalization

## Social Equity

### What does "Social Equity" mean?



**Definition in public administration** (NAPA 2000):

*"The fair, just and equitable management of all institutions serving the public directly or by contract; and the fair and equitable distribution of public services, and implementation of public policy; and the commitment to promote fairness, justice and equity in the formation of public policy."*



Social Equity

≠



Social Equality

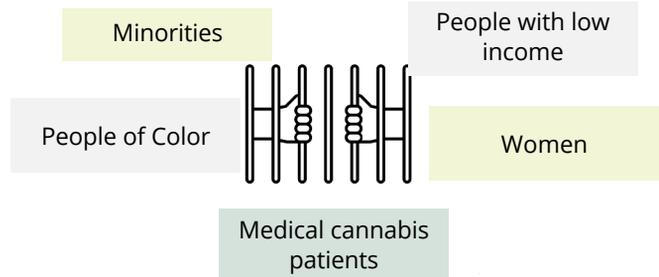
### Social Equity and Cannabis Regulation



#### Goals of Governments' Social Equity Programs:

To bring justice to those who were and are disadvantaged and treated unfairly during the period of drug prohibition policies

#### Groups that have been/are potentially marginalized and/or oppressed by cannabis drug prohibition



- Decades of drug prohibition policies have led to **structural inequality, injustice & stigmatization**
- More and more, cannabis has been legalized for recreational and/or medicinal purposes in numerous states, and some countries, like Germany, are on the verge of doing so
- It is important to focus on how to design the regulation because "legal regulation has the potential to become **a powerful tool to redress decades of criminalization, economic exclusion, and lack of access to appropriate health care**" (IDCP 2020)
- On top, **destigmatization** is necessary and crucial, and could lead to earlier and more targeted addiction prevention measures and services of addiction support (fdr 2019)

### How to Design a Social Equity Program for a Cannabis Industry?

**3 policy categories for regulators to address** (inspired by Title 2021)

1

**Criminal justice reforms** including automatic expungement of past cannabis offenses and rehabilitation

2

**Reinvesting a share of funds** available through legalization to **take socially just measures**

3

Creating a cohesive **cannabis industry licensing framework** with special considerations for people affected by drug prohibition policies



## Social Equity

### 1 Criminal Justice Reforms

- “The comprehensive character of reparation includes **restoring the rights that have been violated** and, if this is not possible, applying compensation, satisfaction and non-repetition measures” (IDPC 2020)
- Criminal justice reforms may include automatic **expungement of past cannabis offenses**, and releases from prison (inspired by Title 2021)
- Possible **rehabilitation measures**, e.g. receiving apprenticeships, training as skilled personnel, etc.

“Good Practice” from the U.S.:



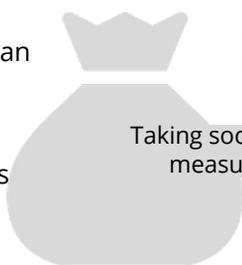
*“The Last Prisoner Project (LPP) is a national, nonpartisan non-profit organization dedicated to cannabis criminal justice reform” (LPP 2022)*

LPP addresses the past and continuing harms of unjust drug policy by “legal intervention, public education and legislative advocacy”

### 2 Reinvesting a Share of Funds available Through Legalization

Estimated **4.7 billion euros per year** can be raised by legalizing cannabis in Germany (Haucap & Knoke 2021)

1. through **additional revenue** (taxes and social security contributions)
2. through **saved expenditure**



...for groups / communities most impacted by prohibition

...for more prevention measures and youth protection (BMG 2022)

### 3 A Cohesive Cannabis Industry Licensing Framework

#### I. Definition of eligible participants

- Varying approaches exist to identify who qualifies for social equity programs
- Common examples for criteria: e.g. residency in specific geographic areas; race; people with own or their family members' past drug arrests and convictions

#### II. Definition of benefits that social equity businesses receive, e.g.

- Access to funds for grants and loans for social equity businesses (important: funding must be available before application processes for licensing starts)
- Access to real estate property or allowance of shared commercial kitchens and cultivation spaces
- Technical assistance with applications, compliance, and operation of a business
- Fee waivers/discounts (e.g. application fees, software fees, tracking fees)
- Advantages in licensing processes (e.g. additional scoring for social equity applicants in processes)
- Exclusive access to a pool of licenses or a specific license type
- Design of different “tracks” of benefits for applicants with different interests in the industry, such as ownership, jobs, executive positions etc.
- ...



## Social Equity

### Social Equity and Cannabis Regulation in Germany



#### Selection of questions to be asked when designing a social equity program

inspired by the 20 principles for the responsible legal regulation of cannabis (IDPC 2020):

- Which groups have been and are marginalized and oppressed by cannabis drug prohibition in Germany? (Data collection needed)
- How can successful amnesty (=“Amnestie”) in light of the Narcotics Law (BtMG §29a, 30,30a) look like?
- How can smaller-scale entrepreneurs be integrated?
- How might licencing barriers (e.g. cost of application, criminal history, upfront commitment costs) for marginalized groups be different from barriers for non-marginalized groups?
- How can people with BtMG offenses receive rehabilitation, e.g. through apprenticeships, training as skilled personnel, etc.?
- How can people with accumulated knowledge that worked in the illicit market get access to newly created jobs in the legal market? (combat skills shortages)



#### Objectives of a social equity program:

- Successful and fair transit of illicit into legal market (IDPC 2020)
- “To actively promote social (and economic) equity applicants” and “racial, ethnic, and gender diversity” among licensees (MRTA 2022; Syracuse 2023)

**Also important:** Consideration of **learnings from international experiences** (U.S. Federal States like New York, Illinois, California etc.) and organizations like the Cannabis Regulators of Colors Coalition



#### Learnings from e.g. New York (MRTA 2022; Syracuse 2023)

- Thinking a **social and economic equity plan** together, especially taking into consideration the potential positive impact of cannabis legalization on employment and earnings (NBER 2022)
- Good practices to develop such a program: The New York cannabis agency created **community roundtables** with representatives from social and economic equity groups

## Social Equity

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# Factsheet: Cannabis legalization

## Products and dosage forms of recreational cannabis

	Cannabis flowers vaporized	Oral extracts	Vapes / E-cigarettes	Edibles
<b>Image</b>				
<b>Target group</b>	Broad consumer group who prefer lung-friendly forms of consumption (without combustion and tobacco)	Broad consumer group who prefer oral ingestion to inhalation	Consumers who appreciate simple, fast and inconspicuous use; occasional users	Broad consumer group, including "pleasure consumers" and occasional users.
<b>Product</b>	Dried cannabis flowers	Extract of active ingredients (e.g. by CO2 / ethanol)	Cannabis extract (partly dissolved in carrier oil) vaporized in e-cigarette	Food products enriched with cannabis extract (e.g. candies, gummy bears, chocolate, pastries, beverages)
<b>Ingredients</b>	Full spectrum of cannabis genetic make-up (cannabinoids, terpenes)	Full extract contains THC, CBD and terpenes	Extracted ingredients / isolate and carrier oil, if applicable	Extracted ingredients dissolved in food or beverages
<b>Application</b>	Inhalation through the use of a vaporizer, which vaporizes active substances in the flower	Oral ingestion of the drops which are absorbed via the digestive tract	Inhalation of the carrier oil, in which the ingredients are dissolved	Oral ingestion, absorption via digestive tract
<b>Pro</b>	<ul style="list-style-type: none"> <li>- No combustion process and no tobacco -&gt; Hardly any absorption of harmful substances</li> <li>- Fast onset</li> <li>- High dosage control</li> <li>- Terpenes are retained and optimally absorbed (Gieringer, 2001; 2004, Hazekamp, 2006; Loflin &amp; Earleywine, 2015)</li> </ul>	<ul style="list-style-type: none"> <li>- Long duration of action</li> <li>- Long product shelf life</li> <li>- No lung damage</li> <li>- Good dosage control (if individual dose is known)</li> </ul>	<ul style="list-style-type: none"> <li>- Rapid onset of action</li> <li>- High dosage control</li> <li>- Long shelf life</li> <li>- With certified carrier oil less lung damage than smoking.</li> </ul>	<ul style="list-style-type: none"> <li>- Advantageous from a health perspective (no lung damage)</li> <li>- Long duration of action</li> <li>- Easy handling</li> <li>- High dosage control, with uniform dosage units</li> <li>- Range of differentiation possibilities</li> <li>- Long shelf life</li> </ul>
<b>Contra</b>	<ul style="list-style-type: none"> <li>- Expensive vaporizer needed</li> <li>- Convinced joint smokers are difficult to convert</li> </ul>	<ul style="list-style-type: none"> <li>- Late onset of action can lead to overdose if dose is unknown</li> </ul>	<ul style="list-style-type: none"> <li>- Could encourage increased use due to ease of use</li> <li>- Long-term effects of carrier oils only initially explored (Jensen et al., 2015)</li> </ul>	<ul style="list-style-type: none"> <li>- Later onset of action and good taste may lead to unintentional overdose</li> <li>- Could stimulate consumption because of combined reward effect (added sugar)</li> <li>- Risk of accidental ingestion by minors</li> </ul>

# Factsheet: Cannabis legalization

## Products and dosage forms of recreational cannabis

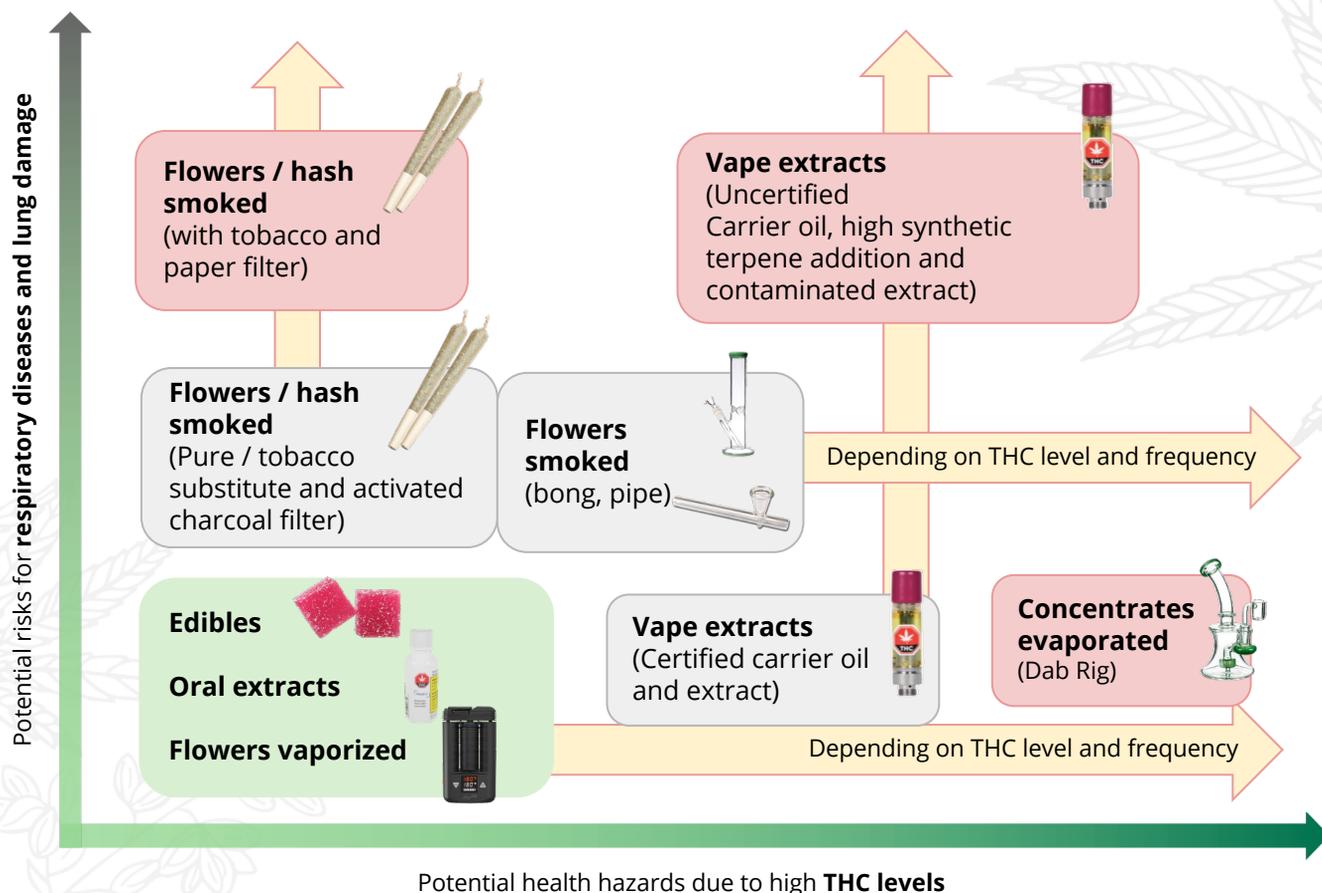
	Cannabis flowers smoked	Hashish	Bong	Dabbing
<b>Image</b>				
<b>Target group</b>	Broad consumer group , traditional consumption type	Broad consumer group , traditional type of consumption	Experienced consumers	Experienced consumers
<b>Product</b>	Dried cannabis flowers	Wax-like product formed when the trichomes (resin glands) of cannabis are concentrated and compacted into a solid block	Glass water pipe in which cannabis flowers and/or hash are smoked	Concentrates (Crystals, Wax, Shatter, Life-Resin, Rosin, Hashish)
<b>Ingredients</b>	Active ingredients of cannabis genetics, but great loss of them due to combustion process, optionally with tobacco or tobacco substitute.	Wax of trichomes and its ingredients, Leaf residues	Active ingredients of the cannabis plant, but loss rate due to water filtration process	High-percentage concentrate from CO2 or BHO extraction with different viscosity and terpene content
<b>Application</b>	Inhalation of smoke produced through the combustion process in joint / pre-roll or pipe	Inhalation of smoke by combustion process in joint, pre-roll or pipe	Inhalation of smoke cooled and purified by water contained in the bong	Dab rig (glass pipe) in which high percentage cannabis concentrate is vaporized
<b>Pro</b>	<ul style="list-style-type: none"> <li>- High dosage control</li> <li>- Fast onset of action</li> <li>- Easy and most common way of consumption</li> <li>- High acceptance by consumers</li> </ul>	<ul style="list-style-type: none"> <li>- Simple and traditional way of extraction and shelf life</li> <li>- Can be produced without large investment</li> <li>- High acceptance by consumers</li> </ul>	<ul style="list-style-type: none"> <li>- Less pollutants than joint, as smoke is filtered and cooled by water (Cozzi, 1995)</li> <li>-No tobacco consumption</li> </ul>	<ul style="list-style-type: none"> <li>- No combustion process</li> <li>- Concentrate has a long shelf life and small volume</li> <li>- Little odor</li> </ul>
<b>Contra</b>	<ul style="list-style-type: none"> <li>- Lung damage due to pollutants associated with the combustion process (especially when combined with tobacco)</li> </ul>	<ul style="list-style-type: none"> <li>- Traditionally consumed through the process of combustion thus resulting in lung damage</li> <li>- Most of the monoterpenes are lost</li> </ul>	<ul style="list-style-type: none"> <li>- High dosage, little dosage control</li> <li>- Loss of some active ingredients in water (Cozzi, 1995)</li> <li>- May cause lung damage (Thu et al., 2013)</li> </ul>	<ul style="list-style-type: none"> <li>- Very high doses and very little dosage control</li> <li>- Can lead to significant overdoses and side effects</li> <li>- High risk of addiction and withdrawal symptoms (Loflin &amp; Earleywine, 2014)</li> </ul>

# Factsheet: Cannabis legalization

## Products and dosage forms of recreational cannabis

### Health damage and THC concentration of products & applications

(Note: The figure was specially created and is only for approximate orientation)



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## Edibles - Cannabis-infused food products

### Why edibles? - Risks of smoking

- Toxins produced during smoking have negative effects on the respiratory system (National Academies, 2017)
- Cannabis is often smoked in a joint along with tobacco, which:
  - Has an addictive potential of 68% at first use (Drugcom, 2011)
  - Is a carcinogen and can cause other diseases (TK, 2020)

### Production & effects of edibles

- Cannabis-infused edibles and beverages have been consumed since 1000 BC (e.g. the drink "Bhang") and are deeply embedded in cannabis culture (Godlaski, 2012)
- THC source material has already been heated/decarboxylated and is active
- Examples of common edibles include THC-enriched cookies, brownies, chocolates, wine gums, candies, or beverages
- After oral ingestion, the active ingredients are absorbed via the digestive tract
- Effect occurs at the earliest after approx. 30 min and reaches peak after approx. 2-4 hours (depending on dose, body weight, stomach filling) (Grotenhermen, 2003)
- Long shelf life, even frozen (depending on MHD of ingredients)
- Easy to take, odorless and discreet
- No inhalation of smoke (thus compliance with non-smoker protection law)
- No expensive vaporization device necessary



### Risks of self-produced edibles

- Unintentional overdose (Barrus et al. 2016)
  - No information about THC content
  - Overestimation of the amount of cannabis source material used
  - Later onset of effects and good taste can lead to overconsumption
- (Accidental) use by children and adolescents (Richards et al., 2017)
  - No child-resistant packaging
  - No warning labels
  - Tendentially found in household bakery and/or candy form.
- Contamination with mycotoxins, salmonella, heavy metals, pesticides, etc. possible if not tested to food standards
- Potential sale in the illegal market without traceability of ingredients

### Advantages of edibles from industrial production

- High dosage control due to precise indication of THC content and uniform dosage units
- Child-resistant packaging and visible warnings
- Certified raw material with transparent manufacturing chain
- Verifiable hygiene during production and analysis for contamination according to food standards and HACCP
- Best before date prevents food poisoning after expiration of ingredients
- List of ingredients prevents incompatibilities and allergic reactions (nut, egg, gluten, etc.)

## Edibles - Cannabis-infused food products

### Possible regulation of edibles

- Production according to food standards, HACCP
- Uniform dosage units with defined THC content and traffic light system (very light=2.5 mg THC (green), light=5 mg (yellow), medium=10 mg (orange) , strong=20 mg (red))
- Sale in child-resistant packaging, or refilling of a reusable child-resistant packaging in the store
- Communicate safer-use guidelines to consumers

### Safer-use guidelines for edibles (Canadian Centre on Substance Use and Addiction, 2019)

1. Read label carefully (for THC and CBD concentration and directions for use).
  - Inexperienced users should not consume more than 2.5 mg of THC and wait for the effects to be felt first
2. The effect of ingesting cannabis lasts longer than inhaling cannabis
  - Effects can last up to 12 hours, with residual effects lasting up to 24 hours
  - Inexperienced users should use edibles in a place where they feel safe and comfortable, accompanied by friends or family members who have experience using these products
3. The effects of oral cannabis ingestion can be more intense than those of inhalation
  - Liver converts THC into a stronger form when taken orally
  - Therefore, inexperienced users should not consume more than 2.5 mg of THC
4. It takes time for the full effect to set in
  - Intoxicating effect starts after about 30 minutes at the earliest and reaches its peak after about 2-4 hours
  - At high doses, residual effects can last up to 12-24 hours after consumption
5. Correct storage of edibles and cannabis products
  - Proper labeling and child-resistant containers which are out of reach and sight of children and pets thereby preventing accidental ingestion
6. No mixed use with alcohol or other substances
  - Simultaneous use of cannabis with alcohol or other substances can significantly increase the risk of over-intoxication and impairment
7. Regular cannabis use may adversely affect mental health
  - Daily or near-daily cannabis use increases risk of dependence and may cause or exacerbate anxiety or depression

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## Hashish / Kief

### Basics Cervantes (2015)

- Hashish: A waxy product formed when the trichomes of cannabis are concentrated and compacted into a solid block
- Kief: The dry matter collected by sieving trichomes.
- Approximately 20-30% THC content, depending on the strain (Statista, 2022; VertavaHealth, 2019)
- Consists of wax and its constituents (cannabinoids, terpenes), as well as leaf debris
- Original form of cannabis extract and deeply rooted in cannabis culture
- Traditional production by hand rubbing the resin from flower and leaf material
- Inhalation of smoke through combustion process in joint, pre-roll, bong or pipe
- However, in legal markets, displacement of hashish by extracts from newer production techniques (CO2, butane, cryo, etc.) (MerryJane, 2019)



Haschisch-Block aus gepressten Trichomen



Kief: Pulver aus gesiebten Trichomen

### Pro Cervantes (2015)

- Simple and traditional form of extraction
- Long shelf life
- Small volume
- Inexpensive machinery needed for production
- Good utilisation of the plants residues/waste materials (leaf material, smaller flowers)

### Contra

- Usually smoked in a joint with tobacco - increases risk of respiratory disease (National Academies, 2017)
- Much manual labor required for production
- In traditional production, most of the volatile monoterpenes are lost (Russo et al. 2021)

### Recommendation

- Sale should be allowed because:
  - Rooted in cannabis culture and high demand for the product
  - As a result, if it is not available for purchase in legal market, it will be sourced from illegal market
  - Production without high investment costs for machinery promotes inclusion of smaller businesses
  - Good utilization of plant residues for holistic use of the cannabis plant
  - Small volume and long shelf life simplify storage and transportation

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# Factsheet: Cannabis legalization

## Oral extracts

### Basics

- Drops for oral administration
- Approved in the medical field according to DAB 2020 monograph "Adjusted Cannabis Extract".
- Consists of full spectrum cannabis extract (with terpenes) or THC/ CBD isolate dissolved in MCT oil
- Onset of action delayed due to absorption in the digestive tract, but longer lasting (after approx. 30 min at the earliest, peak after approx. 2-4 hours (Grotenhermen, 2003))
- Already decarboxylated/heated and effective upon ingestion
- Besides CO<sub>2</sub>-extraction also distillation (in ethanol) possible



Cannabis extract to be taken orally

### Pro

- Oral ingestion does not cause respiratory problems
- Discreet ingestion, without odor
- No device needed for ingestion (e.g. vaporizer)
- Small volume
- Long shelf life
- Easy transport and storage
- Plant residues (leaves, small flowers) can be optimally utilized in extraction process
- Basis for the production of edibles (e.g. cookies with extract)

### Contra

- High investment costs of a CO<sub>2</sub> extraction machine necessary given the presumption that ethanol-based extracts are not allowed

### Recommendation

- Sale should be permitted given:
  - It's an alternative dosage form to ingestion - no combustion process required
  - Easily dosed to recommended dosage with droplet pipette if declared
  - If it is not purchasable in the legal market, it is obtained from the illegal market
  - Good utilization of plant residues for holistic use of cannabis plant
  - Small volume and long shelf life simplify storage and transportation

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# Factsheet: Cannabis legalization

## High percentage extracts

Terpene content

THC-Content

Description	Diamonds/ Crystals	Shatter	Wax	Live resin
Photo				
Characteristics	Small crystals	Brittle, toffee-like extract	Sticky, waxy extract	Soft extract
THC value	approx. 90 %	approx. 80%	approx. 80%	approx. . 40-70%
Application	via Dab Rig alternatively also vape, pipe, bong "infused" joints			

### Pro

- Consumption through vaporization rather than combustion (less respiratory diseases).
- Concentrate has long shelf life and small volume
- Hardly any odor emitted
- Quick onset of action

### Contra

- Very highly concentrated and consequently little dosage control
- Can lead to significant overdoses and side effects
- High risk of addiction and withdrawal symptoms compared to other products (Loflin & Earleywine, 2014)

### Recommendation

- Sell in a regulated manner as the existing demand will be satisfied by the illicit market.
  - Butane gas extraction to produce extracts is extremely dangerous due to high risk of explosion and occurs repeatedly in the illicit market (Top-Online, 2022; DHV, 2017)
- Taxation according to THC content
- Detailed information about risks and side effects at the time of purchase informing consumers



### Sources

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# Factsheet: Cannabis legalization

## E-Vapes

### Basics

- Cannabis extract (partly dissolved in carrier oil), which is vaporized using e-vapes.
- Components are extract / isolate and possibly carrier oil
- The higher the content of the extract (potency), the less carrier oil is required

### Pro

- Fast onset of action
- High dosage control
- Long shelf life
- No burning process and therefore less risk for respiratory diseases than smoking (prerequisite: certified carrier oil, e.g. glycerin, MCT)

### Contra

- Could encourage consumption due to easy handling
- Long-term effects of carrier oils only partially explored (Jensen et al., 2015)

### Risk of illegal vapes

- Illegal vapes without end analysis may be contaminated with synthetic cannabinoids, heavy metals, pesticides, etc. (Guo et al. 2021)
- Illegal vapes may contain vitamin E acetate as a carrier, which was predicted to lead to "vape lung disease" (EVALI) (CDC, 2020)

### Recommendation

- Allow sale of certified vape products
- MCT or glycerol should be used as a carrier oil
- Do not set a THC upper limit, otherwise more carrier oil must be used (with potentially stronger side effects than THC)
- "Disposable" vapes should be avoided as they can only be used once and create additional waste



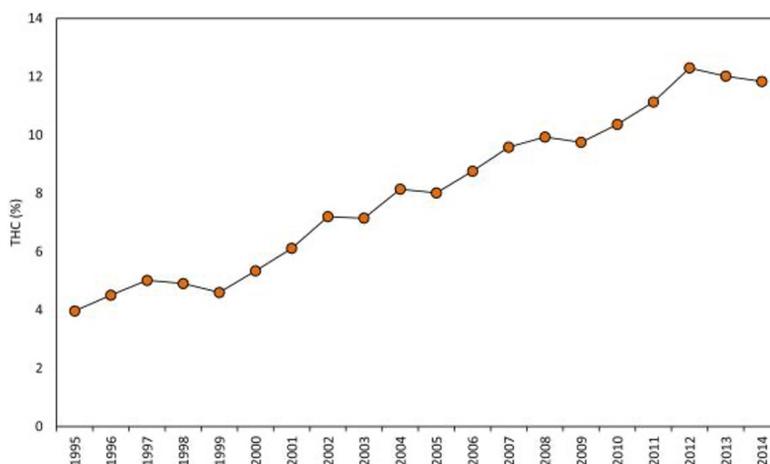
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## THC content

### Status Quo

- The THC content of illicit cannabis products has steadily increased over the past 30 years (ElSohly et al. 2016)
- The most popular cannabis strains usually have more than 20% THC content (Royal Queen Seeds, 2022)
- Enormous increase in yields is achieved through:
  - Breeding for higher potency
  - Optimizing environmental conditions through protected cultivation (exposure, irrigation, temperature, fertilization, plant protection)
  - Use of sinsemilla plants (unpollinated female cannabis plants)



Cannabis flower today



Cannabis Flower from High Times Top Strains 1977

THC content of confiscated cannabis flowers in recent decades (ElSohly et al., 2016)

### Arguments for a THC cap

- With higher THC content, the potential of side effects and addiction increases (Stuyt, 2018; Petrilli et al., 2022)
- Ease of entry for new users with products containing low levels of THC

### Arguments against a THC cap

- Illicit market would continue to thrive with high-THC products
- Frequent users often prefer high THC levels (tolerance, habituation) and would not switch from the illegal to the legal market in case of a THC cap.
- Products in the illicit market may be laced with lethal, synthetic cannabinoids to achieve high potency

## THC content

### International examples of THC ceilings in recreational cannabis

State / Country	Regulation	Status of legislation	Source
<b>Vermont</b>	Flowers max. 30 % THC Extracts max. 60 % THC	Enforced	Mjbizdaily, 2021
<b>Florida</b>	Flowers max. 10 % THC Extracts max. 60 % THC	Not enforced	HB 1455
<b>Massachusetts</b>	Flowers and Vapes max. 10 % THC	Not enforced	HD 2841
<b>Colorado</b>	Max. 15 % THC in all cannabis products		<a href="#">HB21-1317</a>
<b>Montana</b>	Max. 15 % THC in all cannabis products	Not enforced	SB 341
<b>Washington</b>	Extracts max. 30 % THC	Not enforced	HB 1463
<b>Canada</b>	Edibles max. 10mg THC/package Extracts max. 10mg THC/unit or max. 1000mg THC/package Topicals max. 1000mg THC/package flowers without THC additives	Enforced	Cannabis Act
<b>Uruguay</b>	Max 9% THC of commercially grown varieties; No regulation for home cultivation	Enforced	Weedmaps, 2021

### Recommendation for possible regulation

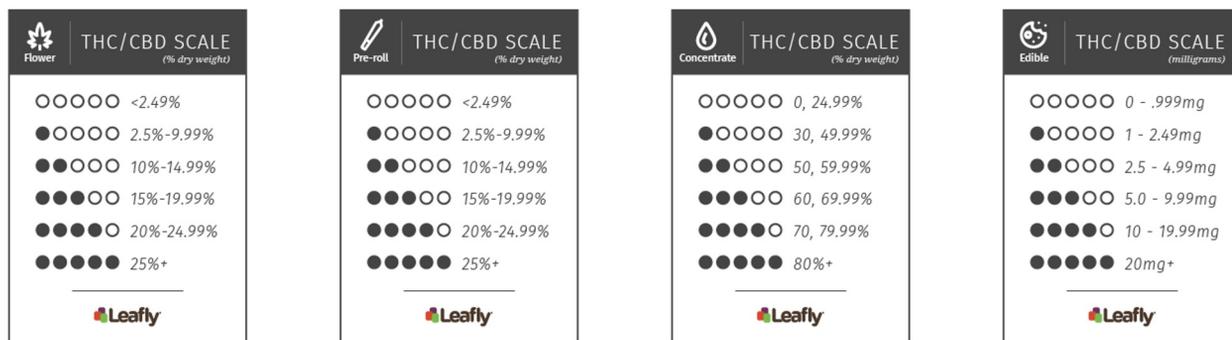
- No THC cap on cannabis flowers and extracts.
- THC upper limit on edibles conceivable (5-20 mg THC per unit of consumption) to avoid unintentional overdoses
- Offer wide range of products with different THC levels so that individual can choose preferred potency
- Tax the THC content to steer consumers towards cheaper products with lower THC content.
- Information on the THC content on the product packaging
- Educate consumers about the potential harm of high THC levels.
- Traffic light system with colors conceivable (red=high, orange=medium, green=low THC content)

# Factsheet: Cannabis legalization

## THC content

### Possible marking of the potency

#### Example point system (Leafly 2017)



THC/CBD scales for different cannabis product categories

#### Example "traffic light system" for flowers

Type	THC-content	CBD-content	Traffic light color
Balanced THC/CBD ratio	6-12%	6-12%	green
Low THC content	<12%	<1%	green
Medium THC content	12-18%	<1%	yellow
High THC content	18-25%	<1%	red

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## Microbiological purity

### Risk of microorganisms

- Plants are constantly exposed to microorganisms from soil, air and water (de Freitas Araújo & Bauab, 2012, Kneifel et al., 2002). Therefore, a certain microbiological colonization is inevitable.
- Risk depends on intended use, the type of product, and potential consumer harm
- Microbiological contamination may:
  - Adversely affect product performance (stability)
  - Alter physical properties and appearance
  - Inactivate active ingredients and excipients in formulation
  - Cause loss of consumer trust
  - Cause active infection by multiplication in host
  - Cause toxicity by oral ingestion or inhalation (salmonella, mycotoxins)
  - Cause allergic hypersensitivity reactions or lung disease in susceptible individuals (Aspergillus species)

### Types of microbiological contamination

#### Plant viruses

No danger for humans



#### Yeasts and molds + spores

- Mold is most common microbiological contaminant
- Botrytis is the most common but rarely causes hypersensitivity reactions (Holmes et al., 2015; Popp et al., 1987; Spijksma et al., 1987)
- Some Aspergillus species (*A. fumigatus*, *A. flavus*, *A. terreus* und *A. niger*) can cause hypersensitivity and pneumonia (Singh, 2014; Panjabi, 2011; Chaudhary, 2011)
- If the immune system is healthy, they are cleared from the lungs (Park et al., 2009; Bellocchio et al., 2005; Chaudhary et al., 2010; Schaffner et al., 1982)
- Risk from mycotoxins extremely unlikely (conditions for high replication not given and degradation starts at 160° C) (Kosalec, 2009; Holmes et al., 2015; Broeke, 1975)

#### Bacteria + spores

- Cannabis is not a potential transmission medium for bacterial pathogens (*Salmonella*, *Listeria*, *E. Coli*) (Holmes et al., 2015)
- However, contamination can result from poor worker hygiene; contaminated soil, fertilizer, and water; and small animals during outdoor cultivation

## Microbial purity

### Measures to ensure microbiological purity

Influencing microbiological growth by:

- Temperature, humidity, and precipitation during pre- and post-harvest periods
- Adherence to basic hygiene measures (Kneifel et al., 2002; Bugno et al., 2006)
- Storage conditions (Busse et al., 2000)

Quality assurance in the process:

- Documentation of all steps in the process
- Rigorous training of all personnel (hygiene, recognition of mold)
- Qualification and monitoring of the HACCP system by authorities (Hoppe, 2005)

Elimination of most microorganisms by:

- Drying
- Irradiation
- Pressure (extraction)

(Holmes et al., 2015)



### Global guideline values for dried plant products

Region	Application	Guideline / Monograph	TAMC CFU/g	TYMC CFU/g	BTGN Bacteria	E.Coli	Salmonella	Source
WHO	Oral (Tea)	Plant material for internal use	≤ 100'000	≤ 1000	≤ 1000	Absence in 10g	Absence in 1g	Cundell, 2019
EU	Inhalation	Ph. Eur. 5.1.4.	≤ 100	≤ 10	Absence in 1g	Absence in 1g	Absence in 1g	Ph. Eur. (7.) 5.1.4.
	Oral (medicinal tea)	Ph. Eur. 5.1.8, category A	≤ 10'000'000	≤ 100'000		≤ 1'000	Absence in 25g	Ph. Eur (9.0) 5.1.8
	Herbal medicinal products (powder drugs)	Ph. Eur. 5.1.8, category C	≤ 100'000	≤ 10'000	≤ 1000	Absence in 1g	Absence in 25g	Ph. Eur (9.0) 5.1.8
	Food tea	VO (EG) Nr. 852/2004 EG-Food-hygiene	Only good practice guidelines, but no maximum values, since it is a natural product and is infused with boiling water					
Australia	Inhalation	TGO 100	≤ 200	≤ 20	Absence in 1g	Absence in 1g	Absence in 1g	TGA, 2020
	Oral (Tea)		≤ 20'000	≤ 200	≤ 100	Absence in 1g	Absence in 10g	TGA, 2020
USA	Inhalation	Cannabis Inflorescence Quality Control Monograph (AHPA)	≤ 100'000	≤ 10'000	≤ 1000	Absence in 1g	Absence in 1g	Holmes et al. 2015
	Oral (AHPA)	Dried processed herbs used in dietary supplements (AHPA)	≤ 10'000'000	≤ 100'000	≤ 10'000	Absence in 10g	Absence in 25g	Cundell, 2019
	Oral (USP)	Dried of powdered botanicals (USP)	≤ 100'000	≤ 1000	≤ 1000	Absence in 10g	Absence in 10g	Cundell, 2019
Canada		Reference to Ph. Eur. or other pharmacopoeia data	Appropriate for the intended use and any reasonably foreseeable use					Government of Canada, 2020
Switzerland	Recreational-Cannabis	Conform with Ph. Eur. 5.1.8, Category A	≤ 10'000'000	≤ 100'000		≤ 1'000	Absence in 25g	BAG, 2021

## Microbial purity

### Recommendations for microbial testing

1. **Dried cannabis flowers for recreational use** should follow the guidelines of **Ph. Eur. 5.1.8,**

**Category C** for "Herbal Medicinal Products":

- **TAMC:** Acceptance criterion:  $10^5$  CFU/g or CFU/mL. Max. acceptable count: 500 000 CFU/g or CFU/mL (Ph. Eur. 2.6.12)
- **TYMC:** Acceptance criterion:  $10^4$  CFU/g or CFU/mL. Max. acceptable count: 50 000 CFU/g or CFU/mL (Ph. Eur. 2.6.12)
- **Bile-tolerant gram-negative bacteria:** Acceptance criterion:  $10^4$  CFU/g or CFU/mL (Ph. Eur. 2.6.31)
- **Escherichia coli:** Absence 1g (Ph. Eur. 2.6.31)
- **Salmonella:** Absence 25 g (Ph. Eur. 2.6.31)
  
- Further tests and limits for "Herbal Medicinal Products":
  - **Foreign materials** (Ph. Eur. 2.8.2): <2%
  - **Loss on drying** (Ph. Eur. 2.2.32): <12%
  - **Pesticide residues:** defined for the 70 most common in Ph. Eur. 2.8.13, others in EC directives and limits in ADI values of FAO-WHO, and compliance with plant protection by the producer
  - **Heavy metals** (Ph. Eur. 2.4.27, Ph. Eur. 2.4.8): Per Kg
    - Cadmium < 1 mg
    - Lead < 5.0 mg
    - Mercury < 0.1 mg
  - **Mycotoxins** (Ph. Eur. 2.8.18, 2.8.22):
    - Aflatoxin B1 < 2 µg/kg
    - Total aflatoxin < 4 µg/kg (Ph. Eur. 2.8.18)
    - Ochratoxin A < 20 µg/kg (Ph. Eur. 2.8.22)

2. **Fresh cannabis** requires additional testing for *Pseudomonas aeruginosa*, *Clostridium botulinum*, and toxigenic *E. coli* (Holmes et al., 2015)

3. **Edible cannabis products should be regulated by health departments and meet the relevant food standards** (Holmes et al., 2015)

4. **Cannabis extracts** (type B1) should follow **Ph. Eur. 5.1.8. category B** guidelines:

- **TAMC:** Acceptance criterion:  $10^4$  CFU/g or CFU/mL. Max. acceptable count: 50 000 CFU/g or CFU/mL (Ph. Eur. 2.6.12)
- **TYMC:** Acceptance criterion:  $10^2$  CFU/g or CFU/mL. Max. acceptable count: 500 CFU/g or CFU/mL (Ph. Eur. 2.6.12)
- **Bile-tolerant gram-negative bacteria:** Acceptance criterion:  $10^2$  CFU/g or CFU/mL (Ph. Eur. 2.6.31)
- **Escherichia coli:** Absence 1 g or 1 mL (Ph. Eur. 2.6.31)
- **Salmonella:** Absence 25 g or 25 mL (Ph. Eur. 2.6.31)

5. A **water activity** of not more than 0.65 is recommended to reduce the potential for microbial contamination (or approximately 14 % ± 2 % Loss on Drying) (Holmes et al., 2015)

## Microbial purity

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# Factsheet: Cannabis legalization

## Production models

### Overview of five production and quality models

Lightly regulated

Highly regulated



1 – Home Cultivation



2 – Cannabis Social Clubs



3 - Agricultural Standard



4 - Herbal medicinal products



5 - Non-sterile pharmaceutical preparations for inhalation

### Production model 1 - Home Cultivation



**Self-supply through home cultivation**

Target group	<ul style="list-style-type: none"> <li>• Hobby gardeners / scientists / growers</li> <li>• Lower-income consumers</li> </ul>
Quality specifications	According to the know-how and preferences of the grower
Cultivation	Outdoor (balcony, garden), or indoor (grow tent)
Manufacturing	According to the know-how and preferences of the grower
Pro	<ul style="list-style-type: none"> <li>• Good for hobby gardeners, low-income consumers</li> <li>• Equal status to other legal drugs and stimulants</li> <li>• Destigmatisation</li> </ul>
Cons	<ul style="list-style-type: none"> <li>• Quality and energy consumption vary with growing method (indoor vs. outdoor) and knowledge of the grower</li> <li>• Potentially higher risk for contamination with inexperienced growers</li> <li>• Protection of minors more difficult to control</li> <li>• No tax revenue for the state</li> </ul>

## Production models

### Production model 2 - Cannabis Social Clubs (CSCs)



Associations for home cultivation

Target group	<ul style="list-style-type: none"> <li>• Associations of consumers for collective cultivation and consumption</li> <li>• Hobby gardeners / scientists / growers</li> <li>• Lower-income consumers</li> </ul>
Quality specifications	<ul style="list-style-type: none"> <li>• Association sets its own quality standards</li> <li>• Membership of passionate and experienced growers</li> <li>• Quality control by organisers and members of the CSC</li> <li>• Random controls by the food authority possible</li> </ul>
Cultivation	As sustainable as possible, according to ENCOD Guidelines and the preferences of the CSCs and its members
Manufacturing	According to ENCOD Guidelines as well as the preferences of the CSC and its members
Pro	<ul style="list-style-type: none"> <li>• Product quality at "craft level" depending on the grower's skills</li> <li>• Sustainable and on-demand production through short supply chains and good demand estimation</li> <li>• Space for cannabis culture and "safe space" for consumption</li> </ul>
Cons	<ul style="list-style-type: none"> <li>• Quality and energy consumption vary with cultivation method and cultivation region</li> <li>• No tax revenue for the state</li> </ul>

### Production model 3 - Agricultural standard



Standard for food tea

Target group	Microbially mostly safe product for consumers with a functioning immune system
Quality specifications	<ul style="list-style-type: none"> <li>• ISO standards, industry standards</li> <li>• Maximum levels of contaminants specified, but only randomly checked by authorities</li> </ul>
Cultivation	GACP in greenhouse facility or open field
Manufacturing	GACP, GAP guidelines, DLMB, 2016, BBodSchG, 2015, HACCP system
Pro	<ul style="list-style-type: none"> <li>• Lower price due to less energy consumption meaning lower investment costs, know-how and analyses</li> <li>• Inclusion of farms resulting in a high number of suppliers</li> </ul>
Cons	<ul style="list-style-type: none"> <li>• Possible higher use of herbicides and pesticides</li> <li>• Possible heavy metal contamination</li> <li>• Long-term inhalation of microbially contaminated product could cause lung damage</li> </ul>

## Production models

### Production model 4 - Herbal medicinal products according to Ph. Eur. 5.1.8., category C



**Standard for herbal medicinal products e.g. powder capsules**

Target group	<ul style="list-style-type: none"> <li>• Microbially a sufficiently safe product for consumers with a healthy immune system</li> <li>• Appropriate quality requirements for recreational cannabis</li> </ul>
Quality specifications	<ul style="list-style-type: none"> <li>• DAC/ NRF Monograph "Cannabis Flowers</li> <li>• European Pharmacopoeia monograph Ph. Eur. 5.1.8 "Microbiological quality of herbal medicinal products for oral use and extracts used in their preparation", category C</li> </ul>
Cultivation	GACP in greenhouse facility or open field
Manufacturing	Global GMP-Standards
Pro	<ul style="list-style-type: none"> <li>• Standard sufficient for consumers with healthy immune systems</li> <li>• Globally high supply of qualified suppliers</li> <li>• Organic and "craft" production can also meet this quality standard</li> </ul>
Cons	<ul style="list-style-type: none"> <li>• People with weakened immune systems should be aware of potential side effects</li> </ul>

### Production model 5 - Non-sterile pharmaceutical preparations for inhalation according to Ph. Eur. 5.1.4.



**Current standard for medical cannabis**

Target group	<ul style="list-style-type: none"> <li>• Microbially safe product for people with a weak immune system</li> <li>• Pharmaceutical quality requirements for medical cannabis</li> </ul>
Quality specifications	<ul style="list-style-type: none"> <li>• DAC/ NRF Monograph "Cannabis flowers"</li> <li>• Monograph Ph. Eur 5.1.4. "Microbiological quality of non-sterile products for pharmaceutical use"</li> </ul>
Cultivation	GACP in high-tech indoor or greenhouse facility
Manufacturing	EU-GMP
Pro	<ul style="list-style-type: none"> <li>• Safe product also for immunocompromised consumers</li> <li>• Constant active ingredient content due to maximum controlled environmental conditions</li> </ul>
Cons	<ul style="list-style-type: none"> <li>• Higher costs in production lead to higher product prices</li> <li>• Limited choice of suppliers due to high investment costs and know-how</li> <li>• Competing with medicinal cannabis market, potential supply deficit for patients</li> <li>• High input of energy and resources needed for production</li> <li>• Sufficient supply probably not guaranteed</li> </ul>

# Factsheet: Cannabis legalization

## Home cultivation

### Home cultivation is already legal in some countries, e.g.:

- Luxembourg: 4 plants allowed for self-cultivation, cultivation not visible to public
- Malta: 4 plants allowed
- Netherlands: 5 plants allowed, area must be fenced, must not disturb neighbors
- Uruguay: 6 plants per household and 480 g storage allowed
- USA: 6 - 15 plants allowed (depending on US state), area must be fenced in

### Potential problems & risks with home cultivation:

- Outdoor cultivation:
  - Contamination (mold, heavy metals, pesticides)
  - Theft and access by minors (if inadequately secured)
  - Crop failure due to poor environmental conditions, wrong choice of varieties, etc.
- Indoor cultivation:
  - High energy consumption (artificial lighting)
  - Risk of water damage & fires in case of improper installation/use of the equipment
  - Contamination also possible



**Product quality depends on the know-how of the grower, growing conditions and equipment**

### Suggestions for regulation:

- Rolles & Murkin (2016):
  - Establish clear limits on the amount of cultivation allowed
  - Prohibition of sale for commercial purposes
  - Age restriction and controlled access to cannabis seeds, plants, and supplies for cultivation
  - Growers have a responsibility to prevent minors accessing the plants
- Cannabis Control Act Bündnis 90/ Die Grünen (2018):
  - Three flowering plants allowed per person (mergers also possible)
  - No access to plants and harvest for children and adolescents
  - Annual harvest must be for private consumption

**"It makes little practical or legal sense to try to enforce a complete ban on self-cultivation for personal use once possession for personal use is legal, and legal supply sources have been established."** ( Rolles & Murkin, 2016)

### Promote education for home growing

- Provide publicly available learning materials to mitigate risks and impart knowledge regarding:
  - Guidance for self-cultivation (including best practices).
  - Plant health
  - Plant hygiene
  - Identification tools for pests, molds, nutrient deficiencies and excesses.

### Sources:

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# Factsheet: Cannabis legalization

## Point-of-sale models

Lightly regulated

Highly regulated



1 - Online shipping



2 - Dispensary with consumption possibility



3 - Luxury goods specialty shop



4 - Cannabis Dispensary



5 - Pharmacy



6 - Operations of the State

Illicit market displacement high

Illicit market displacement low

Tax revenue high

Tax revenues low

### Point of sale model 1 - Online shipping (also in addition to other model)



Online-Shipping

Target group	<ul style="list-style-type: none"> <li>• Adult consumers from all social classes and every region of Germany</li> <li>• Consumers who value discretion and practicality</li> </ul>
Concept	<ul style="list-style-type: none"> <li>• Insured online shipping for nationwide availability</li> <li>• Specialist staff available online for questions and advice</li> <li>• Age verification at time of purchase and at drop-off point</li> <li>• Similar to the North American model</li> </ul>
Presentation	Retailer's website access restricted to persons of legal age. Packaging in discreet shipping box with an age check on delivery
Illicit market	Most widespread displacement, as shipping infrastructure is available throughout Germany and meets convenience factor for consumers (e.g. last mile delivery, courier services)
Tax revenues	High revenues through high volume of sales
Pro	<ul style="list-style-type: none"> <li>• High displacement of the Illicit market due to nationwide available shipping infrastructure</li> <li>• Wide range of products and inexpensive warehousing</li> <li>• Specialist staff can be reached online throughout Germany</li> <li>• Equality of cannabis as a stimulant compared to alcohol and tobacco products</li> <li>• Contactless delivery possible</li> </ul>
Contra	<ul style="list-style-type: none"> <li>• No on-site consultation</li> <li>• Problem that consumers must seek help themselves</li> </ul>

## Point-of-sale models

### Point of sale model 2 - Sociable and supervised consumption



Dispensary with consumption possibility

Target group	<ul style="list-style-type: none"> <li>• Adult users from all social classes</li> <li>• Sociable users who appreciate the cannabis culture</li> </ul>
Concept	<ul style="list-style-type: none"> <li>• Similar to the Dutch coffee shop model or (e.g. Spanish) cannabis social clubs.</li> <li>• Consumption possible within the dispensary</li> <li>• Supervision by specialised staff</li> </ul>
Presentation	<ul style="list-style-type: none"> <li>• Discreet design on the outside, inviting on the inside</li> <li>• Product branding allowed, but still with warnings</li> </ul>
illicit market	Sufficient displacement if many dispensaries with consumption options open and shipping is allowed
Tax revenues	High revenues through high product sales
Pro	<ul style="list-style-type: none"> <li>• Suppression of the illicit market through good service and a wide range of products.</li> <li>• Professional supervision of consumption ("safe space")</li> <li>• Less consumption in public spaces</li> <li>• Destigmatisation and equalisation of cannabis with other stimulants (e.g. consumption of alcohol in restaurants / bars)</li> </ul>
Contra	<ul style="list-style-type: none"> <li>• The social aspect could encourage consumption</li> <li>• May decrease availability in rural areas</li> </ul>

### Point of sale model 3 - Large-scale sales



Luxury good specialty shop

Target group	<ul style="list-style-type: none"> <li>• Adult consumers of all social classes</li> </ul>
Concept	<ul style="list-style-type: none"> <li>• Sale in specialised luxury food shops, e.g. tobacco, e-cigarette or alcohol shops</li> <li>• Sale in lotto/toto shops as a combination model and shop-in-shop concepts are conceivable</li> <li>• Co-existence with cannabis shops is also possible</li> </ul>
Presentation	<ul style="list-style-type: none"> <li>• Same advertising regulations as alcohol or tobacco</li> <li>• Kept in secure storage or behind the counter (like tobacco or hard alcohol)</li> </ul>
illicit market	<ul style="list-style-type: none"> <li>• Very good displacement of the illicit market due to widespread availability</li> <li>• Infrastructure available throughout Germany</li> </ul>
Tax revenues	High revenues through high volume of product sales
Pro	<ul style="list-style-type: none"> <li>• High availability due to existing infrastructure, also in rural areas (Probably) high product variety and good product advice</li> <li>• Health protection of consumers (compared to the illicit market) through quality-assured products and a transparent supply chain</li> <li>• High tax revenues and crowding out of the illicit market</li> </ul>
Contra	<ul style="list-style-type: none"> <li>• Profit maximisation is the focus of the operators</li> <li>• Addiction counselling and prevention more likely to be given by state counselling centres than at the point of sale</li> <li>• Could encourage consumption of several stimulants and games of chance</li> </ul>

## Point-of-sale models

### Point of sale model 4 - Specialised and regulated



Cannabis-Dispensaries

Target group	<ul style="list-style-type: none"> <li>• Adult consumers of all social classes</li> </ul>
Concept	<ul style="list-style-type: none"> <li>• Specialised cannabis shops with a wide range of products</li> <li>• Age verification upon entry</li> <li>• Trained staff and product advice</li> <li>• Operation in combination with local shipping possible</li> </ul>
Präsentation	<ul style="list-style-type: none"> <li>• Discreet design on the outside, inviting on the inside</li> <li>• Product branding allowed, but still with warnings</li> </ul>
illicit market	Sufficient displacement if many dispensaries open and shipping is allowed
Tax revenues	High revenues through high product sales
Pro	<ul style="list-style-type: none"> <li>• Suppression of the illicit market through good service and a wide range of products</li> <li>• Positive for public health with education and addiction counseling provided by trained staff on site</li> </ul>
Contra	<ul style="list-style-type: none"> <li>• Delayed access in rural regions</li> <li>• Success depends on product quality, tax rate and shipping options</li> </ul>

### Point of sale model 5 - Recreational cannabis from the dispensary



Pharmacy

Target group	<ul style="list-style-type: none"> <li>• Older middle class</li> <li>• Consumers with therapeutic concerns</li> </ul>
Concept	<ul style="list-style-type: none"> <li>• Dispensing of recreational cannabis in pharmacies</li> <li>• Use of the pharmacy infrastructure that exists throughout Germany</li> <li>• Advice on addiction and contraindications</li> </ul>
Presentation	Pharmacy design, white product packaging with warnings
illicit market	Insufficient displacement Potential "problem consumers" unlikely to switch from the illicit market
Tax revenues	Only achievable through high tax rate, not through high sales, in turn boosting the illicit market
Pro	<ul style="list-style-type: none"> <li>• Infrastructure of pharmacies available throughout Germany</li> <li>• Qualified advice from pharmacists</li> </ul>
Contra	<ul style="list-style-type: none"> <li>• High price due to pharmacy surcharge and tax rate</li> <li>• illicit market insufficiently suppressed</li> <li>• Dispensing of stimulants in pharmacies unusual</li> <li>• No admission control for minors</li> <li>• Not every pharmacy will include cannabis in its assortment and offer a diverse range of products</li> </ul>

## Point-of-sale models

### Point of sale model 6 - The state as producer and trader



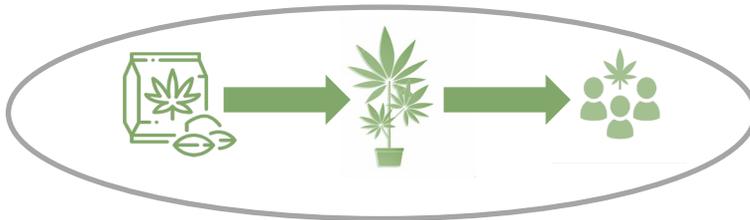
#### Operations of the State

Target group	<ul style="list-style-type: none"> <li>• Older middle class</li> <li>• Adult persons with financial flexibility</li> </ul>
Concept	<ul style="list-style-type: none"> <li>• Cultivation and operation by state agencies to separate cannabis dispensing from sales revenue interests</li> </ul>
Presentation	White product packaging with warnings
illicit market	Almost no displacement as only a small target group is addressed, little product variety and high tax rate
Tax revenues	Hardly any income, due to very few product sales, which can only be compensated for by high tax rate
Pro	<ul style="list-style-type: none"> <li>• Focus on addiction counselling, prevention and youth protection</li> <li>• Centralised production and distribution from a single source</li> </ul>
Contra	<ul style="list-style-type: none"> <li>• Little understanding for cannabis culture and cannabis users</li> <li>• Hardly any displacement of the illicit market due to the high tax rate</li> <li>• No attractive dispensary to divert consumers from the illicit market</li> </ul>

## Cannabis Social Clubs

### What is a Cannabis Social Club?

= a **non-profit association of adult cannabis users** that organizes the cultivation of cannabis for their **personal use**.



Cannabis Social Clubs (CSCs) as closed network

- Supervision of the production and distribution of cannabis to the members of the association.
- Usually covers the entire value chain from seed to final product (cultivation, quality control, transport and distribution)
- Cultivation quantity is based on the needs of the members
- No advertising or sales to non-members
- Membership fees help finance operations



### Cannabis (Social) Clubs?

- The "social" character can also be characterized by consumption opportunities on site, which can be enjoyed with other members
- In some countries, however, this is explicitly not wanted (e.g. in Malta, where the clubs are called "Cannabis Harm Reduction Associations")

### Guidelines for European Cannabis Social Clubs

(European Coalition for Just and Effective Drug Policies, ENCOD)

"Where people have the right to consume, they should be allowed to grow for their own consumption."

(ENCOD Guidelines European Cannabis Social Clubs 2021)

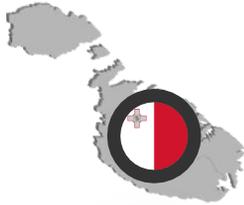


- 1. Open dialogue with authorities:** CSCs are willing to engage in any kind of dialogue with authorities
- 2. Transparency:** CSCs are subject to association law; founding members are subject to background checks; CSCs pay rent, taxes, social security contributions, etc.
- 3. Supply follows demand, not the other way around:** Amount of cannabis to be grown is calculated based on number of members and expected consumption
- 4. Non-profit orientation:** Clubs are run on a non-profit basis; all revenue generated is reinvested in club operations
- 5. Public health focus:** Dispensing and, if applicable, consumption occur on club premises; thereby minimizing the risk of distribution

## Cannabis Social Clubs

### A look at other countries

#### Malta



**Population:** 500.000

**Model:** Legal clubs

**Status quo:** Ongoing licencing process since February 2023

#### Regulatorischer Rahmen

- Only for members, max. 500 members per club
- Max. 4 plants per member
- Max. 50 grams per member per month, no mandatory minimum purchase quantities, no sharing or giving away
- Obligation to register with competent authority
- Regular reporting of the clubs to the authority
- Non-profit
- No outdoor advertising
- At least 250 meters distance from schools and youth centers
- Limit on number of clubs in neighborhood / locality
- No consumption facilities on site

#### Membership criteria

- 18+ years
- Staatsbürgerschaft oder Aufenthaltsgenehmigung

#### Licensing:

The Legalization Act of 2021 established the Authority on the Responsible Use of Cannabis (ARUC). At the beginning of 2023, ARUC announced the licensing criteria for the so-called "Cannabis Harm Reduction Associations". The licensing process has been ongoing since February 2023.

**Licensing criteria** (selection): 1.000 EUR licensing fee, operating permits for retail and for industry and agriculture, inspection of buildings by architect, application with specification of plant number and varieties, nutrients, cultivation method, area and equipment, extensive security system, air filtration and air conditioning system, removal of harvest waste by certified company

**ARUC**

#### Uruguay



**Population:** 3.4 Mio.

**Registered Cannabis Clubs:**

More than 263 in 2021 (Statista 2022)

#### Regulatory framework

- Members only, 15-45 members per club
- Max. 99 cannabis plants in total
- Max. 40 g per member per month
- Registration requirement with competent authority
- Regular reporting by clubs to competent authority
- Non-profit
- No advertising
- At least 150 meters distance from schools and youth centers

#### Criteria for membership

- 18+ years
- Citizenship and permanent residence

#### Distribution models in Uruguay:

Uruguay offers three models for dispensing cannabis for consumption purposes:

**1) home cultivation** for personal consumption (since August 2014); **2) cannabis social clubs** (since October 2014); **3) dispensing in pharmacies** (since July 2017). The three models are mutually exclusive: Consumers must choose a supply channel and register for it with the national cannabis control agency IRCCA.



## Cannabis Social Clubs

### A look at other countries

#### Spain



**Population:** 47,42 Mio.

**Model:** CSCs in legal grey zone

#### Other countries

The approach of decriminalizing home cultivation and cannabis social clubs also exists on a smaller scale in **Belgium** and is also planned as part of the cannabis pilot projects in **Switzerland**.



#### Regulatory framework

- CSCs in Spain operate in a legal grey zone: only some regions allow and regulate CSCs (e.g., Catalonia); federal law prohibits CSCs
- Cultivation for personal use is decriminalized
- Collective consumption and acquisition of cannabis by addicts is not punished

#### CSCs in Spain

- It is estimated that there are between 500 - 1500 clubs
- Most CSCs are unregulated and potentially illegal
- After Barcelona explicitly legalized CSCs, the Supreme Court reclassified them as illegal

#### United Kingdom



**Population:** 67,33 Mio.

**Model:** CSCs with focus medicinal cannabis

#### CSCs in the UK

- CSCs are very different from other countries because they are constructed by and for patients
- Developed in response to the lack of reimbursement for medical cannabis
- Approximately 160 CSCs have been established since 2011

#### Regulatory framework

- Home cultivation is illegal
- UKCSC association guidelines exist
- Cannabis use, possession and trafficking are illegal under current UK legislation

## Cannabis Social Clubs

### How could CSCs look in Germany?

#### Legal anchoring of associations



- **§ 9 Fundamental Law** guarantees **freedom of association**
- The constitutional limits of freedom of association are specified in the **Law on Associations (VereinsG)**
- The private law status of associations is regulated in the **Civil Code (§§ 21 to 79 BGB)**

#### Definition according to German law

Association of several persons // not geared to economic business success // acts as a single entity under one name // represented by a board of directors

#### Political cornerstones



Selection of the **Cannabis-Cornerstone-Paper 2-Pillar-Model** (BMG, 12.04.23):

- **Members:** Number limited to max. 500 members per association, minimum age of 18 years and domicile or habitual residence in Germany.
- **Contributions:** Membership dues to cover cost price, staggered according to dispensing volume (if applicable, with basic flat fee and additional amount per gram dispensed)
- **Cannabis dispensing:** Limited per member (max. 25 g cannabis per day, max. 50 g per month, max. 7 seeds or 5 cuttings per month)
- **Quality assurance / control:** Licensing and monitoring are carried out by state authorities, among other things with regard to compliance with quantity, quality and youth protection requirements, and with spot checks and on-site visits
- **Consumption premises:** Consumption is prohibited on the premises of the association
- **Cultivation and harvesting:** Quantities are geared towards meeting demand incl. reporting and documentation obligations

#### Recommendations for policy implementations:

- According to the ENCOD CSC Guidelines (2021), any connection of cannabis clubs with the **illegal market** should be prevented.
- This could be addressed in a regulatory way, for example, with **tracking of products** from seed to delivery to the member, as well as effective controls
- Evaluate **on-site consumption spaces** as an option for supervised, lower-risk consumption rather than displacement into private or public spaces

#### Germany's club landscape

**Numerous Cannabis Social Clubs** have been or are being founded already today



2022: Founding of an **umbrella organization** of German clubs (already published key points for cannabis legalization)



**However:** Cannabis **cannot currently be legally grown** in clubs, this would require a change in the law and **licensing** of CSCs

## Cannabis Social Clubs

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## Pilot projects enabling the controlled sale of recreational cannabis

### Why Pilot Projects?

**Pilot projects are the first step towards an evidence-based, progressive drug policy**



"The aim is to learn more about the advantages and disadvantages of controlled access to cannabis and to obtain a sound scientific basis for possible decisions on the regulation of cannabis use." (BAG 2022)



### Legal Basis in Germany

§ 3 (2) Narcotics Act (BtMG: Permission to traffic narcotics)

"A permit for the narcotics specified in Annex I may be granted by the Federal Institute for Drugs and Medical Devices only in exceptional cases for **scientific purposes or other purposes that serve public interest.**"

Since the 1990s, various parties have attempted to use this legal basis to submit applications to the Federal Institute for Drugs and Medical Devices (BfArM) for municipal pilot projects (cf. [overview](#) DHV 2022, akzept e.V. 2022). So far no one has achieved approval. With the introduction of a new law on cannabis legalisation incl. an exclusion of cannabis and THC from the Narcotics Act, as envisaged in the cornerstone paper ([October 2022](#)), the legal basis of such an application could be changed.

### Recommendations for Decision-Makers

Pilot projects should be engineered to answer questions tailored to nation-specific conditions thereby ensuring valid data results. In turn this will allow future socially relevant (political) decisions to be taken from an informed perspective. The following aspects should be given special attention in the design and implementation of projects in this country:

#### 1) Conception & Data Collection

- Introduction of **nationwide pilot projects** to ensure comparable data across federal states
- Establish several **independent advisory and evaluation committees**, e.g. as seen in the [Netherlands](#)
- Collect **data before** the start of the pilot project, **during** the project phase and **after** completion for evaluation, e.g. within the framework of these **categories**:

#### Health

- Health, Youth and Consumer Protection
- Development of consumption
- Cannabis dependence and addictive behaviour
- Mental and behavioural disorders
- Experiences with early intervention in problematic use
- Side effects and interactions
- Hospitalisation rate

#### Economy & Finance

- Tax revenues (amount, federal distribution, type of tax revenue, etc.)
- Other economic and labour market effects
- Reduction of bureaucracy
- Effects on black market and medicinal cannabis market
- General market figures (cultivation, import, distribution, licensed shops, quantities sold)

#### Criminality & Security

- Effects on the development of crime and illegal cannabis trade
- Violations of the regulations for the protection of minors
- Road safety, security
- Experience with the regulations on fines and penalties
- Number of Narcotic Drugs proceedings before and after legalisation

**Optional: Individualised data collection at micro level:** Clinical study programme over 5-10 years with the participation of at least 3 larger communities (cities).

## Pilot projects enabling the controlled sale of recreational cannabis

### 2) Allowing Imports in Regard to Climate Protection and Sustainability

Taking into account EU and international law, cannabis imports are permitted for scientific and medical purposes. Imports from European and non-European countries should be promoted within the framework of pilot projects with a view to the following aspects:

1

#### Climate Protection and Conservation of Resources

Cannabis production indoors (=indoor cultivation) is **much more energy and CO2 intensive** than in a greenhouse (=greenhouse) or in a field (=outdoor cultivation), as these data show:



- CO2 footprint of production: **2.300 - 5.200 kg CO2 / 1 kg cannabis** = equivalent to **burning 900 - 2.000 litres petrol**
- Energy consumption for lighting and environmental control: up to **5.000 kilowatt hours (kWh) of electricity / kg of dried flowers**.
- This means: The indoor production of the estimated demand of 400 t / year for the recreational market in Germany corresponds to the entire household electricity consumption of Cologne, the fourth largest German city with over 1.1 million inhabitants (tni 2022)



#### Sustainability

- The evaluation result after the project phases for the controlled distribution of cannabis is not known.
- The construction of new, **energy- and cost-intensive production and processing facilities** for cannabis, which may only be used during the project phase, is **not advisable** in terms of sustainability.

2



3

#### Imports as Part of Social Justice



Allowing imports from traditional producer countries as a **development-oriented approach** in German drug policy during the transition from the illegal to the legal market

#### → Relevant Criteria for the Approval of Imports in Pilot Projects:

- Approval of imports from European and non-European countries
- Preference for the production of cannabis in greenhouses or outdoors with guaranteed product quality (see [Factsheet Produktion Models](#))
- Preference for producers who attach importance to sustainability & climate protection: e.g. use of solar energy; commitment to CO2 neutrality or CO2 reduction
- Refrain from building CO2- and energy-intensive indoor production facilities in Germany

## Pilot projects enabling the controlled sale of recreational cannabis

### Are There Already Pilot Projects in Europe?



#### 1) Netherlands: Controlled Cannabis Supply Chain Experiment

- The controversial **coffee shop policy** in the Netherlands states: the sale and consumption of pleasure cannabis is tolerated - production and trade are prohibited.
- In 2017, the Dutch government initiated the **supply chain experiment** to provide results on how controlled cannabis can be legally supplied to coffee shops and what effects result (Government of Netherlands 2023).
- **10 municipalities** are supposed to participate, the start has been delayed several times. Among other things, because it was not possible to open business accounts. Expected start: autumn 2023 (Tagesspiegel Background, 23.03.2023)



#### 2) Switzerland: Pilot Testing for Cannabis for "Recreational" Purposes

##### Initial Situation

- The Swiss parliament has passed an amendment to the Narcotics Act (BetmG), which has been in force since May 2021
- Article 8a BetmG allows for the conduct of local and time-limited scientific pilot trials with cannabis for "pleasure purposes".
- Details of the application procedure are regulated in the Ordinance on Pilot Trials under the Narcotics Act (BetmPV) (BAG 2022)

##### Framework

- **Location:** One or more municipalities
- **Period:** Maximum 5 years
- **Participants:** Maximum 5000 persons per pilot trial
- **Origin of cannabis:** If possible produced in Switzerland according to organic regulations, otherwise imports possible
- **Products:** Cannabis flowers, processed products, THC limit of 20%
- **Points of sale:** Pharmacies, cannabis social clubs or specialised shops
- **Conditions of participation:** Residence in the canton, existing cannabis use, age of majority, not suffering from contraindications
- **Distribution:** Only against payment, sales limit per month
- **Prohibition:** Passing on to third parties, advertising and consumption in public places

##### Procedure

1. Planning of a trial by study management
2. Selection of manufacturing partners
3. Submission of the applications
4. Review and approval of applications by the Federal Office of Public Health (FOPH)
5. Implementation of the pilot trials (up to 5 years)
6. Evaluation of the data by the study management and the FOPH
7. Scientific basis for future regulation of cannabis

## Pilot projects enabling the controlled sale of recreational cannabis

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## Information and advertising



### Goals of fact-based information

- Information about the **advantages of legal cannabis products** over illegal products (e.g. quality)
- Information about the effects as well as potential side effects and dangers
- Targeted education of consumers promotes health protection and differentiation from the illicit market

## Arguments for & against regulated information & advertising

- **Destigmatization**
- **Differentiation from the illegal market** (Meadows, 2019)
  - The illegal market does not need to advertise because it is already established
  - Advertising bans make it difficult for legal cannabis providers to build awareness
- **Differentiation of emerging brands from each other**
  - Differences in product quality (high, medium, low)
  - Company values (e.g. sustainable, inclusive, innovative)
- **Differentiation of individual products from each other**
  - To avoid misleading sales
  - Criteria for differentiation:
    - Manufacturing (organic vs. conventional vs. pharmaceutical; local vs. imported)
    - Odor, taste (terpene spectrum and total content)
    - Effect (e.g. calming, stimulating, creative etc. due to a specific cannabinoid as well as terpene content)
    - Form of application and its advantages
    - Variety name (recognition value)

Marketing activities could influence the **extent** and **patterns of drug use** (Rolles & Murkin, 2016)

Minors could see advertisements and be **enticed to use** (Rolles & Murkin, 2016)

### Recommendations for regulation

- Permitting information and advertising given that the **intention to buy exists**
- Avoidance of misleading information and subsequent sales
- No advertising if there is no intention to buy
- **Conduct educational campaigns** ("protective demarketing") that promote responsible consumption but do not seek to completely prevent or eliminate consumption (Wesley, Murray 2021) (similar to the "Know Your Limit" alcohol campaign)
- Launch educational campaigns early **before the law takes effect**

## Information and advertising

### 1. Specifications as for alcohol (Deutscher Bundestag, 2021)



#### Advertising allowed:

- In print media, internet, TV (from 6 p.m.), radio, sponsoring

#### Not permitted:

- Advertising to minors
- Effect claims
- Present high potency in a positive way

**Pro:** Best solution against the illicit market, equality with alcohol, destigmatisation

**Contra:** Could arouse curiosity among non-users and young people, normality could create a trivialising impression

### 2. Specifications as for tobacco (Bundesregierung, 2020)



#### Advertising allowed:

- On posters at the direct point of sale

#### Not permitted:

- Advertising in print media, TV, radio, internet, outdoor advertising, sponsoring.
- Free distribution of products

**Pro:** Equality to tobacco, illicit market is suppressed more effectively, consumers are reached, product differences can be communicated

**Contra:** Could arouse curiosity among non-consumers

### 3. Advertising to professionals and consumers (Government of Canada, 2019)



#### Advertising allowed:

- Newsletter to persons of legal age
- On own website with age verification
- Within the shop/at the point of sale
- Branding of product packaging

**Pro:** Advertising only to existing customers, no additional incentive to consume

**Contra:** Insufficient displacement of the illicit market, no equality with legal drugs and stimulants thereby perpetuating stigma

### 4. Advertising only to professionals (Heilmittelwerbegesetz, 1965)



Same requirements as for medicinal cannabis

- Advertising only in the form of product information to professionals (pharmacies, staff in specialist shops)
- White product packaging

**Pro:** No consumption incentives whatsoever

**Contra:** Product differences difficult to communicate, hardly any education, illicit market displacement difficult

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Open

Restrictive

# Factsheet: Cannabis legalization

## Cannabis tax

### 1. Proposal BvCW e.V. (2022)



Tax on THC content  
10 € on 1.000 mg THC  
(e.g. 22 % THC/g = 2,20 € tax)

**Pro:** Linking tax to THC content in each product class; inexpensive tax rate to maximize fight against illicit market

**Contra:** Reliable analyses and stability data necessary

### 2. Proposal Prof. Dr. Haucap (2021)



Fixed tax  
Cannabis flower 4,5 €/g

**Pro:** Simple calculation; no potency counterfeiting

**Contra:** No cost incentive for consumers to buy less potent products

### 3. Proposal Green Party "CannKG" (2018)



Tax by product category  
- Cannabis flower 4 €/g  
- Hashish 5 €/g  
- Extracts 6 €/g

**Pro:** Coupling of price to higher THC concentration

**Contra:** No coupling to THC content, differences within the product categories

### 4. Proposal Pivot Regulatory (2021)



Tax based on the THC content of the flowers  
- High THC content 8 €/g  
- Medium THC content 5 €/g  
- Low THC content 2 €/g

**Pro:** Linking the tax to THC product class; limiting health consequences by making consumption more expensive

**Contra:** Too high tax rate leads to insufficient illicit market suppression

High illicit market displacement

Little illicit market displacement

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## Cannabis in road traffic

### Why can cannabis use be dangerous for road traffic?

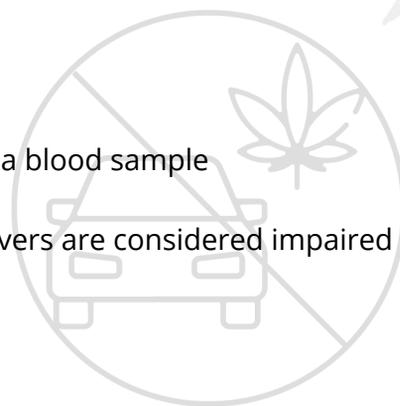
- Acute cannabis intoxication can impair cognitive and psychomotor skills required for safe driving behaviour (Pearlson et al., 2021; Verstraete and Legrand, 2014; Compton, 2017b; Beirness, 2017)
- Cannabis intoxication is linked with a higher likelihood of being involved in a road traffic accident (Wong et al., 2014; Asbridge et al., 2012; Li et al., 2012)
- Unclear how residual blood levels may affect crash risk (Compton, 2017a; EMCCDA, 2018)
- Risk of drinking and driving is much higher (Rogeberg & Elvik, 2016; EMCCDA, 2012, EMCCDA, 2018; Compton, 2017 a,b)

### What drug tests and detection options are available?

Common practice:

1. Checking the driver's behaviour
2. Saliva test to check for THC content
3. If the result of the saliva test is positive: further test with a blood sample

If the THC concentration in the blood exceeds the legal limit, drivers are considered impaired (EMCCDA, 2018)



### Problems with analysis:

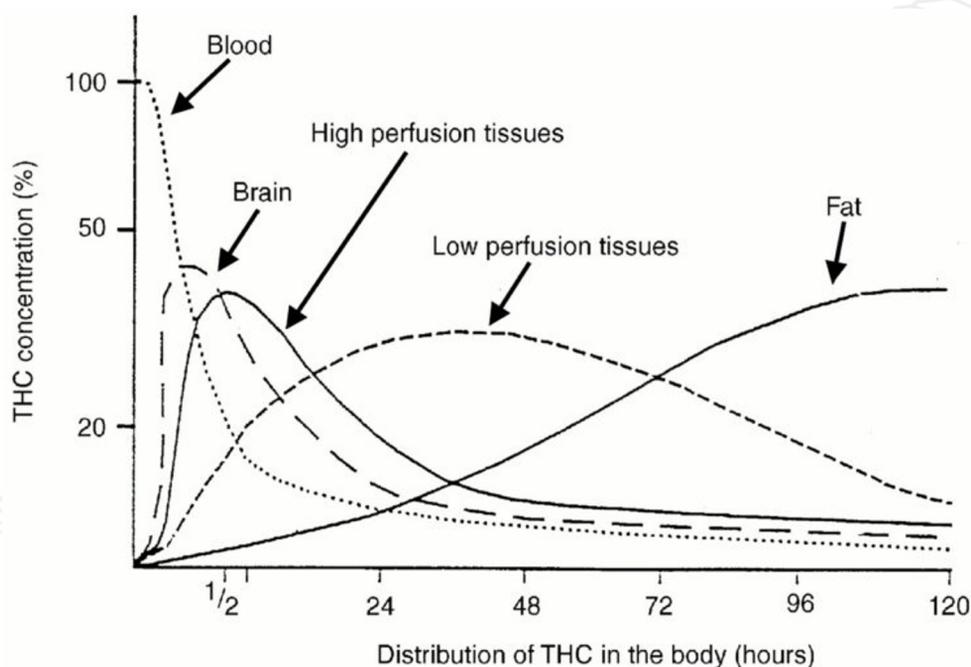
- Often results of saliva and blood tests do not match
- Presence of THC in blood does not necessarily mean that drivers were impaired by cannabis at the time of the accident (Beirness, 2017; Compton, 2017a)
- Cannabis use is tested in a way that is practical for police to implement and acceptable to the public, even if the scientific basis for doing so is weak (Hall, 2018)
- Values have a weak pharmacological and epidemiological basis (Compton, 2017a; Pearlson et al., 2021)
- Blood THC levels serve to deter cannabis use rather than protect public safety (Quilter & McNamara 2016)

# Factsheet: Cannabis legalization

## Cannabis in road traffic

### Metabolisation of THC

- After inhalation of cannabis, there is initially a very steep rise in THC concentration in the blood, then a rapid drop (Compton, 2017a)
- Peak of impairment is 20 to 40 minutes after inhalation (Sewell et al., 2009), even if the THC peak in the blood has long been passed
- Due to storage in adipose tissue, THC can be detected in the blood at very low concentrations long after impairment (EMCCDA, 2018; Heustis, 2005)



Metabolization of THC (Ashton 2001)

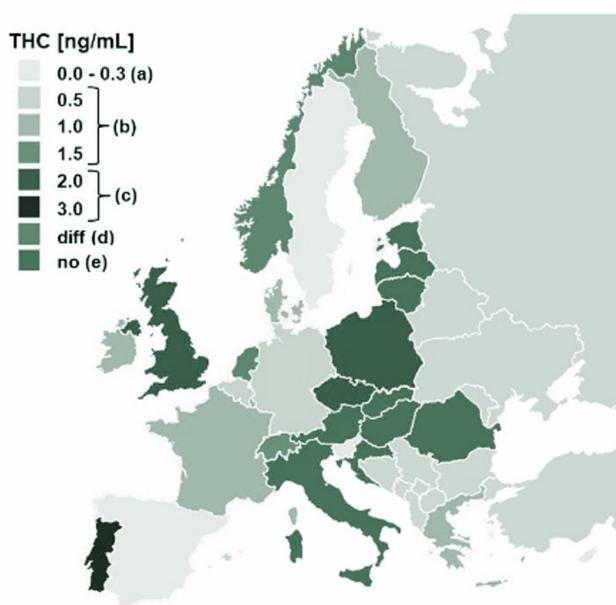
### Factors influencing the impairment of driving ability

- Inhalation or oral intake
- Frequency of use
- Mixed use with e.g. alcohol (Wolff & Johnston, 2014; EMCCDA, 2018)
- Different types of cannabis can produce different subjective experiences in users, which can affect driving safety (Burt et al., 2021)

## Cannabis in road traffic

### Which limit is recommended by experts?

- Germany: Tolerance limit 1.0 ng/ml THC (zero tolerance) (StVG § 24a), but cannabis patients are allowed to participate in road traffic if they are not impaired in their driving ability due to medication
- THC concentration in the blood of 3.7 ng/ml (Berghaus et al., 2010) comparable to impairment of 0.05% (0,5 mg/ml) blood alcohol concentration
- Colorado: impairment may be present at 5 ng/ml THC (Pardo 2014)
- Expert committees have recommended concentrations of 5 ng/ml (UK) (Wolff et al., 2013) or 7 ng/ml (Ramaekers et al., 2004)
- Georg Wurth (DHV) has called for an increase to 10 ng/ml (Bundestag, 2021)



Europäische Grenzwerte für THC im Blut

Legal limit concentrations of THC in blood in some European countries (BAG, 2020)

### Recommendations for regulatory adjustments

- Raise the tolerance level for recreational and medicinal cannabis
- Introduction of a drug test that determines the state of intoxication and not the residual value
- Penalties commensurate with the risk to road safety (Hughes, 2017; Ramaekers, 2017; Vindenes, 2017)
  - Graduated penalties according to the level of THC concentration in the blood
  - Higher penalties for repeated driving while impaired
  - Higher penalties for mixed use
- Referral to drug counselling or treatment (EMCCDA, 2018)

## Cannabis in road traffic

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# Factsheet: Cannabis legalization

## Dealing with treaties under international law

### Germany's membership in relevant UN treaties under international law:

- UN Single Convention on Narcotic Drugs (1961), incl. Protocol Amending the Single Convention (1972), so-called "UN Single Convention".
- UN Convention on Psychotropic Substances (1971)
- UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)



### Principle of the UN Single Convention on Narcotic Drugs (1961):

"Each contracting party shall prohibit the extraction, manufacture, export, import, possession, use and trafficking of such narcotic drugs when, in view of the conditions prevailing in its state, this is the most appropriate means of protecting public health and welfare." (Art. 2)

→ **Exception: Medical and scientific use**

## Four possible scenarios for dealing with the UN Single Convention

<b>Resignation (without re-entry):</b> <ul style="list-style-type: none"><li>- Termination according to Art. 46</li><li>- Termination: on July 1st of a year with effect from January 1st of the following year</li><li>- e.g. termination by July 1, 2022 = resignation at the end of 2022</li><li>- e.g. termination between July 2, 2022 and July 1, 2023 = withdrawal at the end of 2023</li><li>- Risk: Withdrawal of Germany from the entire international drug policy (not only cannabis); restriction of accessibility of cannabis as a medicine</li></ul>	<b>Exit and re-entry subject to cannabis:</b> <ul style="list-style-type: none"><li>- Termination according to Art. 46</li><li>- Re-entry with reservation according to Art. 50: Considered admitted unless vetoed by at least one third of the members within 12 months</li><li>- Termination period as for resignation; re-entry possible immediately (effective 30 days after declaration)</li><li>- Examples: Bolivia (coca)</li><li>- Risk: Veto right of member countries on re-entry</li></ul>
<b>Inter se Modification:</b> <ul style="list-style-type: none"><li>- Modification of international treaty between two or more parties (Art. 41 VCLT 1969)</li><li>- Allows the option of a bilateral trade treaty while maintaining the UN Single Convention vis-à-vis other states</li><li>- Imports to Germany only possible with export license of the contracting party</li><li>- Prerequisite and risk: other member states must not be adversely affected in their interest in the UN treaty</li></ul>	<b>Violation of the convention:</b> <ul style="list-style-type: none"><li>- Only national cultivation possible, no import</li><li>- Substantive reasoning: conflicting obligations under international law force to adjust regulation regarding cannabis</li><li>- Examples: Canada, Uruguay</li><li>- Risk: Sanctions</li></ul>

### Sources:

- Boister NB, Jelsma M (2018). Inter se modification of the UN drug control conventions: An exploration of its applicability to legitimise the legal regulation of cannabis markets. *International Community Law Review*. 20(5). 456-492.
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- United Nations (1961, 1971, 1972, 1988): International Drug Control Conventions <https://www.unodc.org/unodc/en/commissions/CND/conventions.html>

# Factsheet: Cannabis legalization

## Dealing with EU law

### Cannabis in the Schengen Convention ("SDÜ")



Germany, as a member state of the European Union, has committed itself: *"to prohibit the direct or indirect supply of narcotic drugs and psychotropic substances of all kinds, including cannabis, and the possession of such substances for the purpose of supply or export, taking into account existing United Nations conventions, all measures necessary to prevent illicit traffic in narcotic drugs."*

(Schengen Convention Art. 71 (1)) → **Exception: Medical and scientific use**

### Four possible scenarios for dealing with the Schengen Agreement

<b>Amendment of the agreement:</b> <ul style="list-style-type: none"><li>- Due process for amending the Schengen Agreement</li><li>- Duration: 19 months on average</li><li>- <b>Risks:</b> Time delay, required approval of a qualified majority (at least 55% of the member states in the Council and at least 65% of the EU population)</li></ul>	<b>Violation of the agreement:</b> <ul style="list-style-type: none"><li>- Underlying argumentation: For the purpose of health protection and the protection of minors the regulations regarding cannabis have to be adapted nationally</li><li>- <b>Risk:</b> Initiation of infringement proceedings against Germany by the EU Commission before the European Court of Justice</li></ul>
<b>Amendment of international treaties with additional states:</b> <ul style="list-style-type: none"><li>- Joint procedure for amending the underlying international treaties: e.g. adaptation of the UN Single Convention and/or deletion of cannabis from Annex I of the WHO recommendation</li><li>- Forming associations with like-minded states such as the Netherlands, Luxembourg, Portugal, Spain, Malta, Canada, Uruguay, South Africa and individual US states (e.g. Colorado, California, etc.).</li><li>- <b>Risks:</b> Veto of the other contracting states and the subsequent time delay</li></ul>	<b>Introduction of pilot projects:</b> <ul style="list-style-type: none"><li>- (Initially) introduction of pilot projects for recreational cannabis with scientific monitoring</li><li>- No complete legalization of the entire value chain</li><li>- Simultaneous effort by Germany at the European level to amend the Schengen Convention</li><li>- <b>Risks:</b> Stuck in pilot projects as well as no guarantee of nationwide supply in the medium and long term and thus continued existence of the illicit market; loss of economic potential</li></ul>

### Excursus: Assessment of the EU Framework Decision 2004/757/JHA according to CannKG:

The draft cannabis control law by Bündnis 90/Die Grünen discusses how to deal with the EU Framework Decision 2004/757/JHA. According to the draft, the legalization of recreational cannabis would not be in conflict with said law, as the Framework Decision only prohibits trade "without corresponding authorization". Accordingly, a state-permitted trade in cannabis would take place with authorization. The EU Schengen Agreement is not explicitly addressed in the CannKG.

### Sources

- Auswärtiges Amt (2000): Schengen-Besitzstand <https://www.auswaertiges-amt.de/blob/207796/39215de0d45f5190a7febc2f89668baf/schengenbesitzstand-data.pdf>
- Deutscher Bundestag (2018): Drucksache 19/819. "Entwurf eines Cannabiskontrollgesetzes (CannKG). <https://dserver.bundestag.de/btd/19/008/1900819.pdf>
- David Nutt (2022): How to Regulate Cannabis: A Practical Guide. TRANSFORM Policy Foundation.
- European Council of the European Union (2021). Qualified majority. <https://www.consilium.europa.eu/en/council-eu/voting-system/qualified-majority/>
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