Cannabis legalization

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Factsheet: Cannabis legalization

Why should recreational cannabis be legalized?

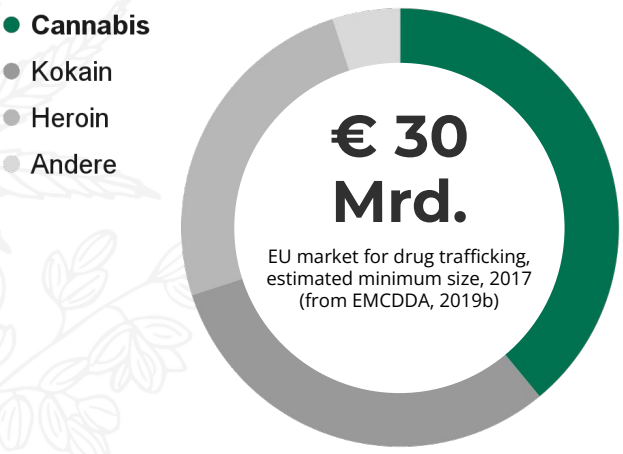
Status quo

- **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 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 generat 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

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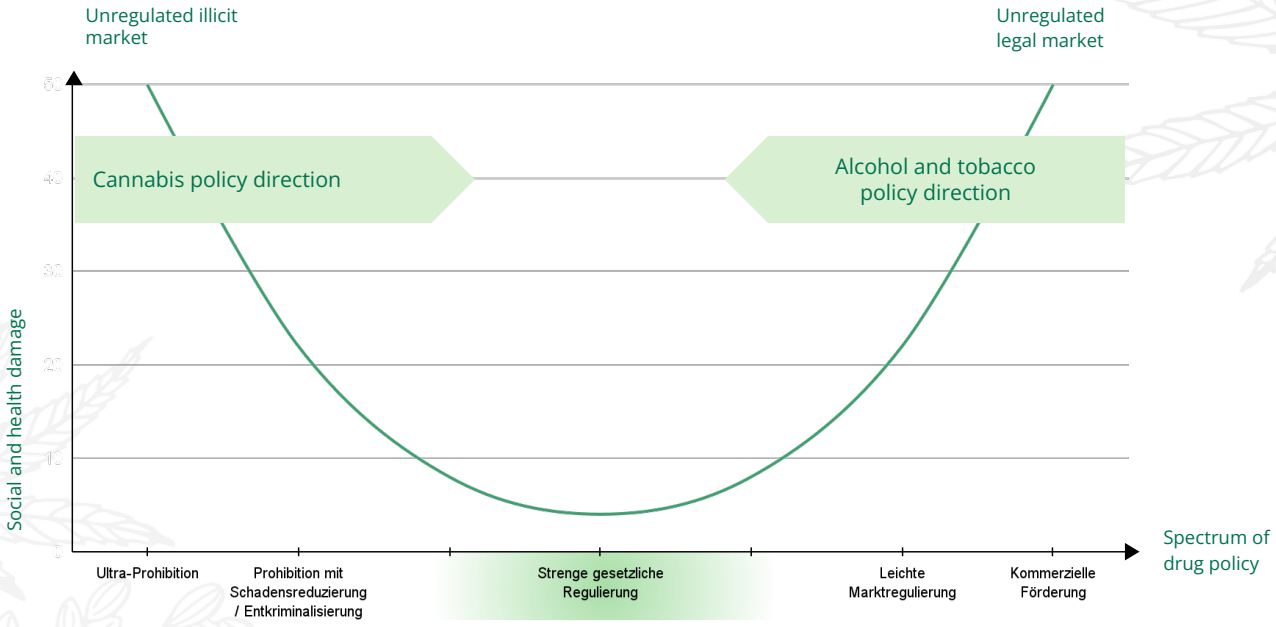
Factsheet: Cannabis legalization

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)

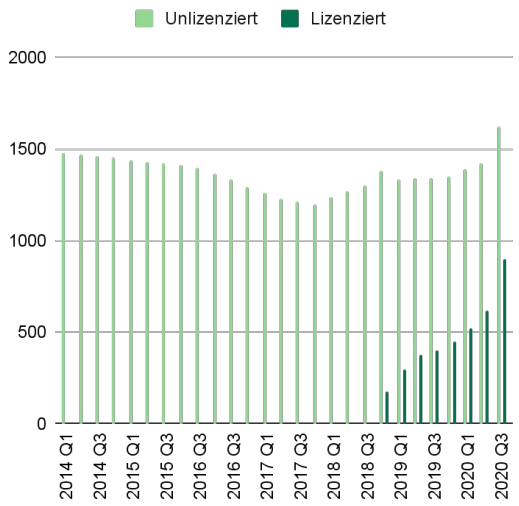
Improvement of public safety
- Reduction of criminal activities, "gang wars"
- Reduction of income sources and the resulting power for players in the illicit market

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

Sources

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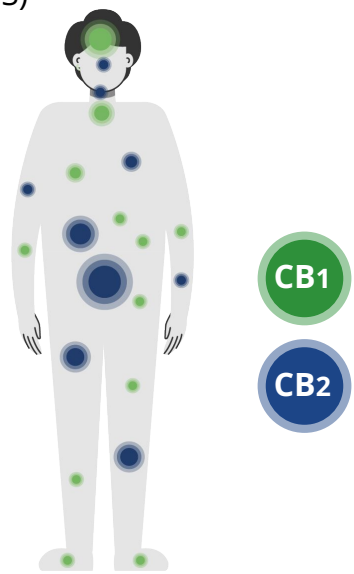
Factsheet: Cannabis legalization

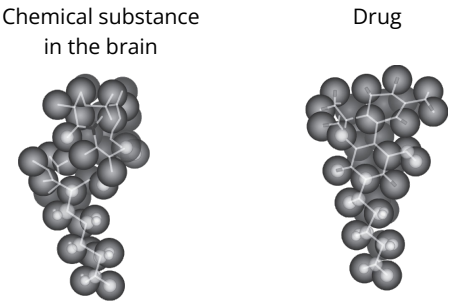
Cannabis use by adults

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)



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

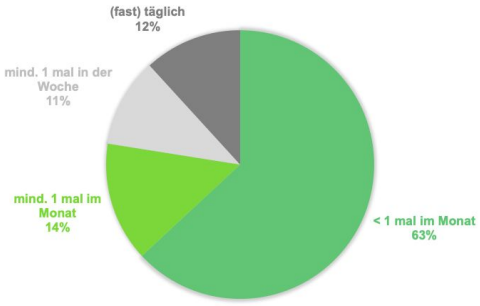
Possible short-term side effects of THC:

- 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)



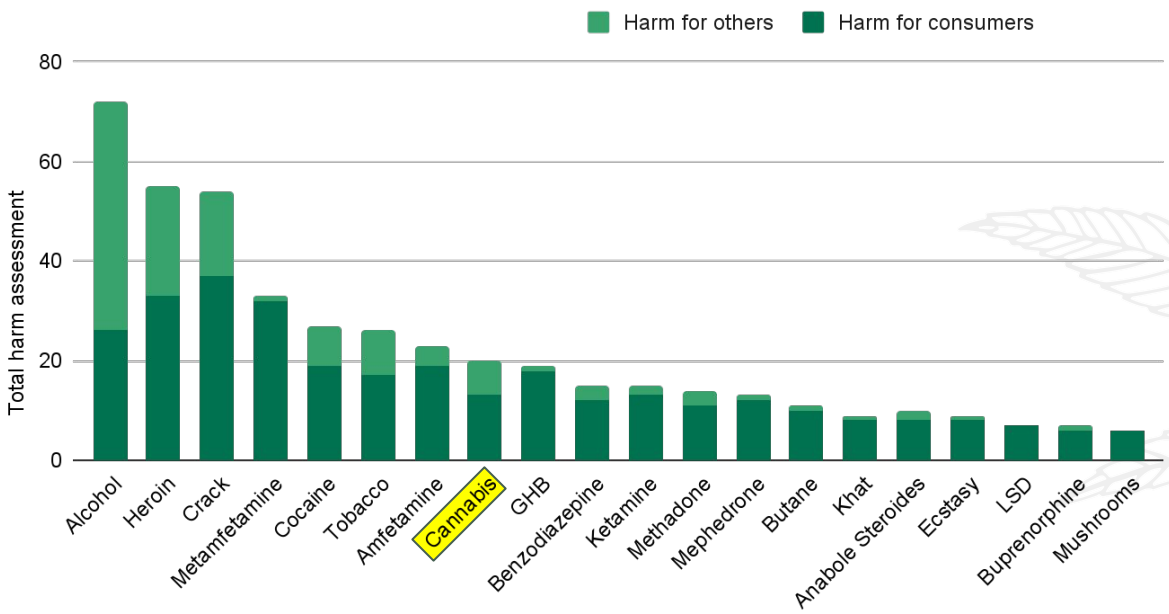
Consumption frequencies of the 12-month users (ESA, 2018)

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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Factsheet: Cannabis legalization

Youth protection

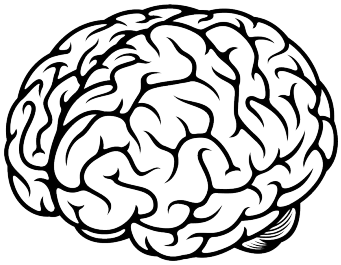
Frequent cannabis use may lead to cognitive impairment in adolescents

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 to 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

Factsheet: Cannabis legalization

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/
- Colorado (USA): Purchasable cannabis education materials for various grade levels
  https://marijuana-education.com
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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

Products and dosage forms of recreational cannabis

	Cannabis flowers vaporized	Oral extracts	Vapes / E-cigarettes	Edibles
Image				
Target group	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.
Product	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)
Ingredients	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
Application	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
Pro	- No combustion process and no tobacco -> Hardly any absorption of harmful substances - Fast onset - High dosage control - Terpenes are retained and optimally absorbed (Gieringer, 2001; 2004, Hazekamp, 2006; Loflin & Earleywine, 2015)	- Long duration of action - Long product shelf life - No lung damage - Good dosage control (if individual dose is known)	- Rapid onset of action - High dosage control - Long shelf life - With certified carrier oil less lung damage than smoking.	- Advantageous from a health perspective (no lung damage) - Long duration of action - Easy handling - High dosage control, with uniform dosage units - Range of differentiation possibilities - Long shelf life
Contra	- Expensive vaporizer needed - Convinced joint smokers are difficult to convert	- Late onset of action can lead to overdose if dose is unknown	- Could encourage increased use due to ease of use - Long-term effects of carrier oils only initially explored (Jensen et al., 2015)	- Later onset of action and good taste may lead to unintentional overdose - Could stimulate consumption because of combined reward effect (added sugar) - Risk of accidental ingestion by minors

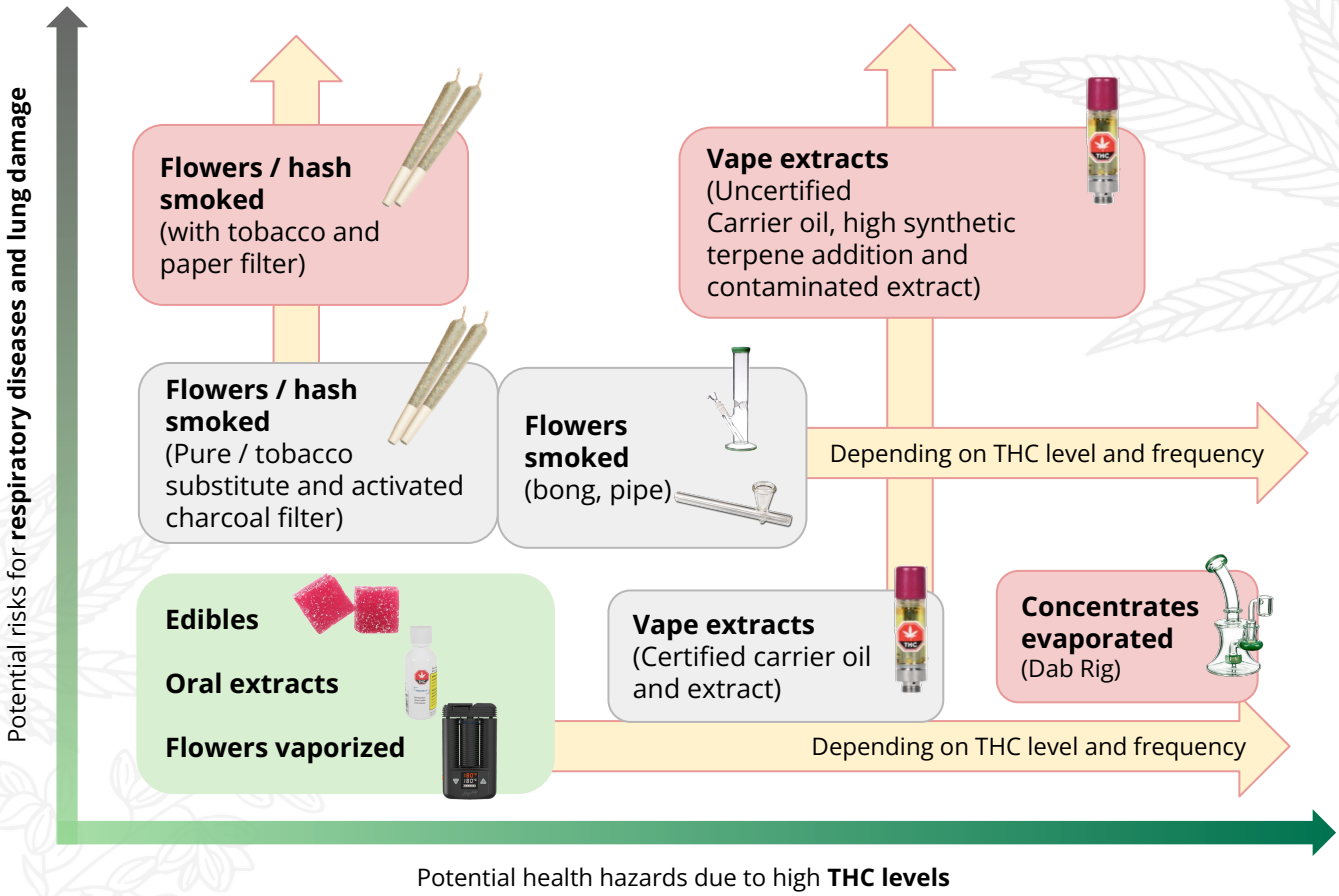
Products and dosage forms of recreational cannabis

	Cannabis flowers smoked	Hashish	Bong	Dabbing
Image				
Target group	Broad consumer group , traditional consumption type	Broad consumer group , traditional type of consumption	Experienced consumers	Experienced consumers
Product	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)
Ingredients	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
Application	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
Pro	- High dosage control - Fast onset of action - Easy and most common way of consumption - High acceptance by consumers	- Simple and traditional way of extraction and shelf life - Can be produced without large investment - High acceptance by consumers	- Less pollutants than joint, as smoke is filtered and cooled by water (Cozzi, 1995) -No tobacco consumption	- No combustion process - Concentrate has a long shelf life and small volume - Little odor
Contra	- Lung damage due to pollutants associated with the combustion process (especially when combined with tobacco)	- Traditionally consumed through the process of combustion thus resulting in lung damage - Most of the monoterpenes are lost	- High dosage, little dosage control - Loss of some active ingredients in water (Cozzi, 1995) - May cause lung damage (Thu et al., 2013)	- Very high doses and very little dosage control - Can lead to significant overdoses and side effects - High risk of addiction and withdrawal symptoms (Loflin & Earleywine, 2014)

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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Factsheet: Cannabis legalization

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.)

Factsheet: Cannabis legalization

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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Factsheet: Cannabis legalization

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 (CO_2, 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

Sources

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- VertavaHealth (2019): https://vertavahealth.com/blog/hashish-vs-marijuana/

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 CO2-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 CO2 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

Sources

- Grotenhermen (2003): Pharmacokinetics and pharmacodynamics of cannabinoids. Clin Pharmacokinet. 2003;42(4):327-60. doi: 10.2165/00003088-200342040-00003. PMID: 12648025.

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)


Dab Rig

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

Sources

- CDC (2020): https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#what-we-know
- Guo et al. (2021): Major Constituents of Cannabis Vape Oil Liquid, Vapor and Aerosol in California Vape Oil Cartridge Samples. Frontiers in Chemistry, 21 June 2021 | https://doi.org/10.3389/fchem.2021.694905
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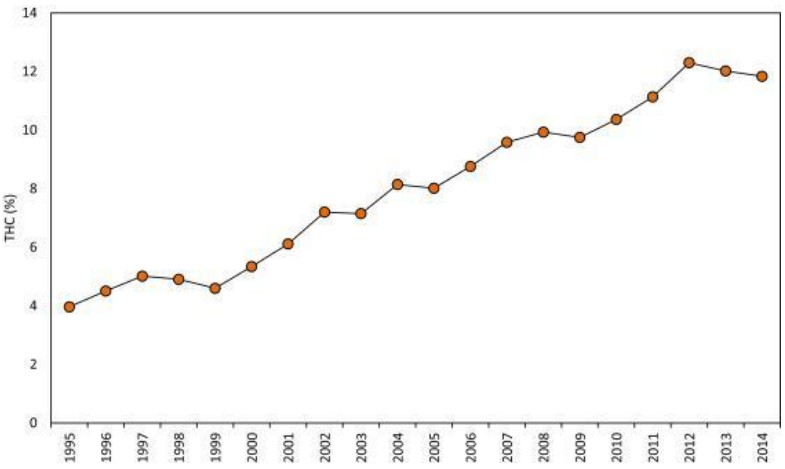
Factsheet: Cannabis legalization

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 from High Times Top Strains 1977



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

Cannabis flower today

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
Vermont	Flowers max. 30 % THC Extracts max. 60 % THC	Enforced	Mjbizdaily, 2021
Florida	Flowers max. 10 % THC Extracts max. 60 % THC	Not enforced	HB 1455
Massachusetts	Flowers and Vapes max. 10 % THC	Not enforced	HD 2841
Colorado	Max. 15 % THC in all cannabis products		HB21-1317
Montana	Max. 15 % THC in all cannabis products	Not enforced	SB 341
Washington	Extracts max. 30 % THC	Not enforced	HB 1463
Canada	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
Uruguay	Max 9% THC of commercially grown varieties; No regulation for home cultivation	Enforced	Weedmaps, 2021

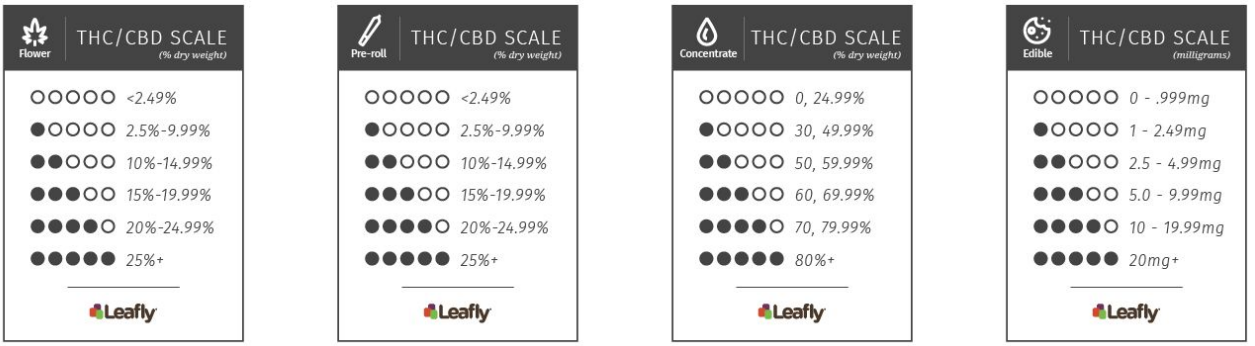
Recommendation for possible regulation

- 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)

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**

Sources

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Sanity Group

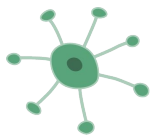
Factsheet: Cannabis legalization

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; Spieksma 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

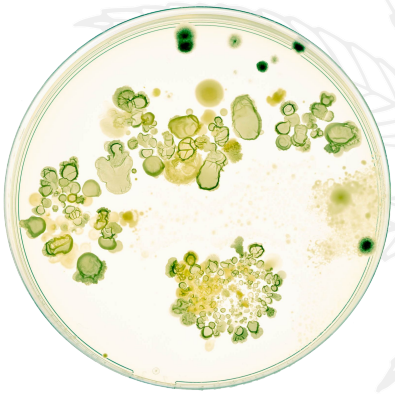
Influencing microbiological growth by:
- Temperature, humidity, and precipitation during pre- and post-harvest periods
- Adherence to basic hygiene measures (Kneifel et al., 2002; Bugno et al., 2006)
- Storage conditions (Busse et al., 2000)

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					LGL Bayern , 2012
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
Switzer-land	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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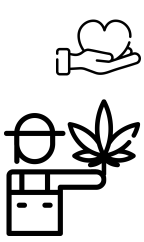
Factsheet: Cannabis legalization

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	• Hobby gardeners / scientists / growers • Lower-income consumers
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	• Good for hobby gardeners, low-income consumers • Equal status to other legal drugs and stimulants • Destigmatisation
Cons	• Quality and energy consumption vary with growing method (indoor vs. outdoor) and knowledge of the grower • Potentially higher risk for contamination with inexperienced growers • Protection of minors more difficult to control • No tax revenue for the state

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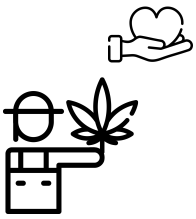
Production models

Production model 2 - Cannabis Social Clubs (CSCs)



Associations for home cultivation

Target group	• Associations of consumers for collective cultivation and consumption • Hobby gardeners / scientists / growers • Lower-income consumers
Quality specifications	• Association sets its own quality standards • Membership of passionate and experienced growers • Quality control by organisers and members of the CSC • Random controls by the food authority possible
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	• Product quality at "craft level" depending on the grower's skills • Sustainable and on-demand production through short supply chains and good demand estimation • Space for cannabis culture and "safe space" for consumption
Cons	• Quality and energy consumption vary with cultivation method and cultivation region • No tax revenue for the state

Production model 3 - Agricultural standard

Standard for food tea

Target group	Microbially mostly safe product for consumers with a functioning immune system
Quality specifications	• ISO standards, industry standards • Maximum levels of contaminants specified, but only randomly checked by authorities
Cultivation	GACP in greenhouse facility or open field
Manufacturing	GACP, GAP guidelines, DLMB, 2016, BBodSchG, 2015, HACCP system
Pro	• Lower price due to less energy consumption meaning lower investment costs, know-how and analyses • Inclusion of farms resulting in a high number of suppliers
Cons	• Possible higher use of herbicides and pesticides • Possible heavy metal contamination • Long-term inhalation of microbially contaminated product could cause lung damage

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	• Microbially a sufficiently safe product for consumers with a healthy immune system • Appropriate quality requirements for recreational cannabis
Quality specifications	• DAC/ NRF Monograph "Cannabis Flowers • 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
Cultivation	GACP in greenhouse facility or open field
Manufacturing	Global GMP-Standards
Pro	• Standard sufficient for consumers with healthy immune systems • Globally high supply of qualified suppliers • Organic and "craft" production can also meet this quality standard
Cons	• People with weakened immune systems should be aware of potential side effects

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

Current standard for medical cannabis

Target group	• Microbially safe product for people with a weak immune system • Pharmaceutical quality requirements for medical cannabis
Quality specifications	• DAC/ NRF Monograph "Cannabis flowers" • Monograph Ph. Eur 5.1.4. "Microbiological quality of non-sterile products for pharmaceutical use"
Cultivation	GACP in high-tech indoor or greenhouse facility
Manufacturing	EU-GMP
Pro	• Safe product also for immunocompromised consumers • Constant active ingredient content due to maximum controlled environmental conditions
Cons	• Higher costs in production lead to higher product prices • Limited choice of suppliers due to high investment costs and know-how • Competing with medicinal cannabis market, potential supply deficit for patients • High input of energy and resources needed for production • Sufficient supply probably not guaranteed

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

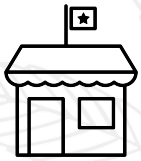
1 - Online shipping

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	• Adult consumers from all social classes and every region of Germany • Consumers who value discretion and practicality
Concept	• Insured online shipping for nationwide availability • Specialist staff available online for questions and advice • Age verification at time of purchase and at drop-off point • Similar to the North American model
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	• High displacement of the Illicit market due to nationwide available shipping infrastructure • Wide range of products and inexpensive warehousing • Specialist staff can be reached online throughout Germany • Equality of cannabis as a stimulant compared to alcohol and tobacco products • Contactless delivery possible
Contra	• No on-site consultation • Problem that consumers must seek help themselves

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Point-of-sale models

Point of sale model 2 - Sociable and supervised consumption

Dispensary with consumption possibility

Target group	• Adult users from all social classes • Sociable users who appreciate the cannabis culture
Concept	• Similar to the Dutch coffee shop model or (e.g. Spanish) cannabis social clubs. • Consumption possible within the dispensary • Supervision by specialised staff
Presentation	• Discreet design on the outside, inviting on the inside • Product branding allowed, but still with warnings
illicit market	Sufficient displacement if many dispensaries with consumption options open and shipping is allowed
Tax revenues	High revenues through high product sales
Pro	• Suppression of the illicit market through good service and a wide range of products. • Professional supervision of consumption ("safe space") • Less consumption in public spaces • Destigmatisation and equalisation of cannabis with other stimulants (e.g. consumption of alcohol in restaurants / bars)
Contra	• The social aspect could encourage consumption • May decrease availability in rural areas

Point of sale model 3 - Large-scale sales

Luxury good specialty shop

Target group	• Adult consumers of all social classes
Concept	• Sale in specialised luxury food shops, e.g. tobacco, e-cigarette or alcohol shops • Sale in lotto/toto shops as a combination model and shop-in-shop concepts are conceivable • Co-existence with cannabis shops is also possible
Presentation	• Same advertising regulations as alcohol or tobacco • Kept in secure storage or behind the counter (like tobacco or hard alcohol)
illicit market	• Very good displacement of the illicit market due to widespread availability • Infrastructure available throughout Germany
Tax revenues	High revenues through high volume of product sales
Pro	• High availability due to existing infrastructure, also in rural areas • (Probably) high product variety and good product advice • Health protection of consumers (compared to the illicit market) through quality-assured products and a transparent supply chain • High tax revenues and crowding out of the illicit market
Contra	• Profit maximisation is the focus of the operators • Addiction counselling and prevention more likely to be given by state counselling centres than at the point of sale • Could encourage consumption of several stimulants and games of chance

Point-of-sale models

Point of sale model 4 - Specialised and regulated

Cannabis-Dispensaries

Target group	• Adult consumers of all social classes
Concept	• Specialised cannabis shops with a wide range of products • Age verification upon entry • Trained staff and product advice • Operation in combination with local shipping possible
Präsentation	• Discreet design on the outside, inviting on the inside • Product branding allowed, but still with warnings
illicit market	Sufficient displacement if many dispensaries open and shipping is allowed
Tax revenues	High revenues through high product sales
Pro	• Suppression of the illicit market through good service and a wide range of products • Positive for public health with education and addiction counseling provided by trained staff on site
Contra	• Delayed access in rural regions • Success depends on product quality, tax rate and shipping options

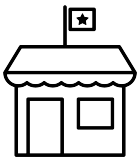
Point of sale model 5 - Recreational cannabis from the dispensary

Pharmacy

Target group	• Older middle class • Consumers with therapeutic concerns
Concept	• Dispensing of recreational cannabis in pharmacies • Use of the pharmacy infrastructure that exists throughout Germany • Advice on addiction and contraindications
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	• Infrastructure of pharmacies available throughout Germany • Qualified advice from pharmacists
Contra	• High price due to pharmacy surcharge and tax rate • illicit market insufficiently suppressed • Dispensing of stimulants in pharmacies unusual • No admission control for minors • Not every pharmacy will include cannabis in its assortment and offer a diverse range of products

Point-of-sale models

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



Operations of the State

Target group	• Older middle class • Adult persons with financial flexibility
Concept	• Cultivation and operation by state agencies to separate cannabis dispensing from sales revenue interests
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	• Focus on addiction counselling, prevention and youth protection • Centralised production and distribution from a single source
Contra	• Little understanding for cannabis culture and cannabis users • Hardly any displacement of the illicit market due to the high tax rate • No attractive dispensary to divert consumers from the illicit market

Factsheet: Cannabis legalization

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**

Factsheet: Cannabis legalization

Information and advertising

Open

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

Restrictive

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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

Sources

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Factsheet: Cannabis legalization

Cannabis in road traffic

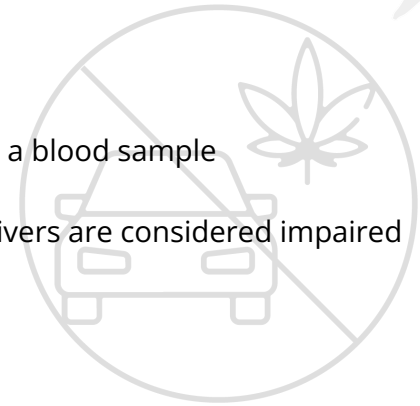
Why can cannabis use be dangerous for road traffic?

- 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 alcohol may affect crash risk (Compton, 2017a; EMCCDA, 2018)
- Risk of drinking and driving is much higher (Rogeberg & Elvik, 2016; EMCDDA, 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)

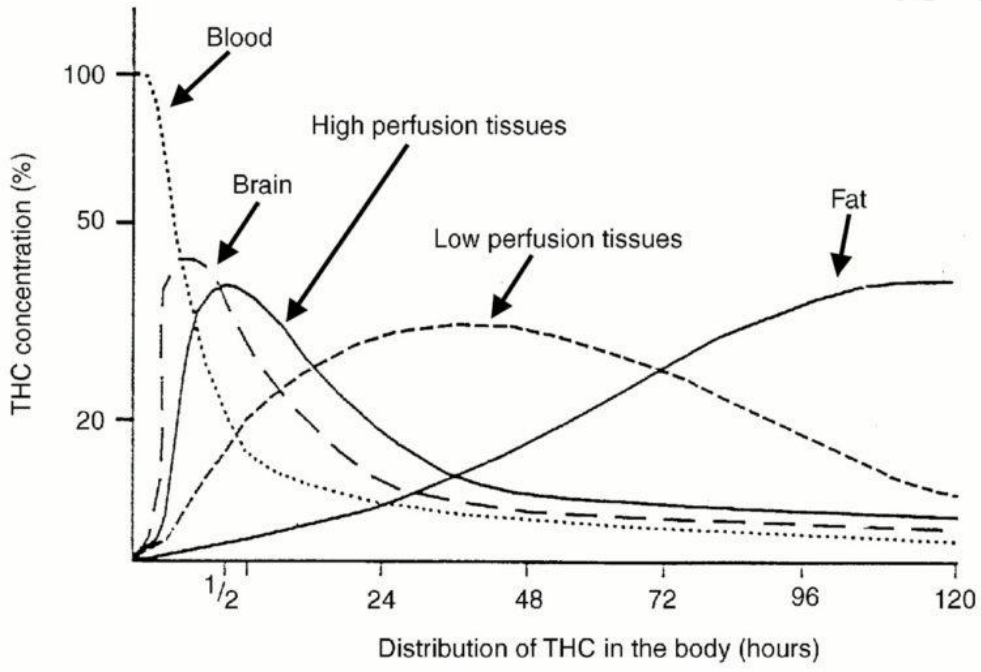
Problems with analysis:

- 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)

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)

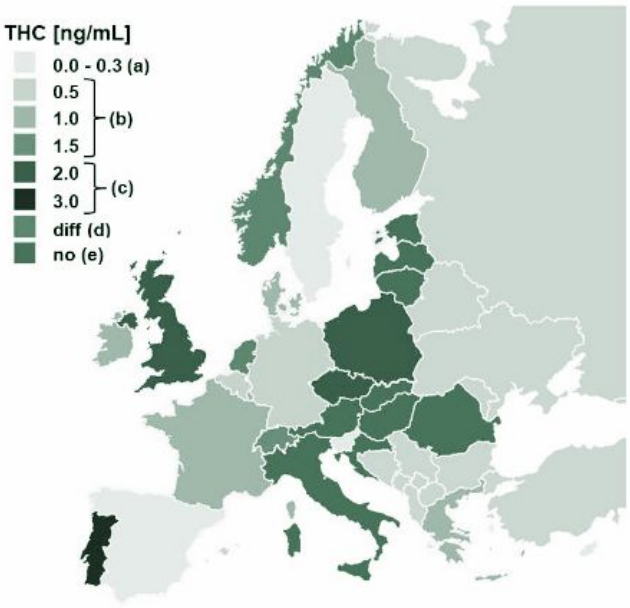
Factors influencing the impairment of driving ability

- 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)



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

Resignation (without re-entry):

- Termination according to Art. 46
- Termination: on July 1st of a year with effect from January 1st of the following year
- e.g. termination by July 1, 2022 = resignation at the end of 2022
- e.g. termination between July 2, 2022 and July 1, 2023 = withdrawal at the end of 2023
- Risk: Withdrawal of Germany from the entire international drug policy (not only cannabis); restriction of accessibility of cannabis as a medicine

Exit and re-entry subject to cannabis:

- Termination according to Art. 46
- Re-entry with reservation according to Art. 50: Considered admitted unless vetoed by at least one third of the members within 12 months
- Termination period as for resignation; re-entry possible immediately (effective 30 days after declaration)
- Examples: Bolivia (coca)
- Risk: Veto right of member countries on re-entry

Inter se Modification:

- Modification of international treaty between two or more parties (Art. 41 VCLT 1969)
- Allows the option of a bilateral trade treaty while maintaining the UN Single Convention vis-à-vis other states
- Imports to Germany only possible with export license of the contracting party
- Prerequisite and risk: other member states must not be adversely affected in their interest in the UN treaty

Violation of the convention:

- Only national cultivation possible, no import
- Substantive reasoning: conflicting obligations under international law force to adjust regulation regarding cannabis
- Examples: Canada, Uruguay
- Risk: Sanctions

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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

Amendment of the agreement:

- Due process for amending the Schengen Agreement
- Duration: 19 months on average
- Risks: 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)

Violation of the agreement:

- Underlying argumentation: For the purpose of health protection and the protection of minors the regulations regarding cannabis have to be adapted nationally
- Risk: Initiation of infringement proceedings against Germany by the EU Commission before the European Court of Justice

Amendment of international treaties with additional states:

- 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
- 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.).
- Risks: Veto of the other contracting states and the suqsequent time delay

Introduction of pilot projects:

- (Initially) introduction of pilot projects for recreational cannabis with scientific monitoring
- No complete legalization of the entire value chain
- Simultaneous effort by Germany at the European level to amend the Schengen Convention
- Risks: 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

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.

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