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

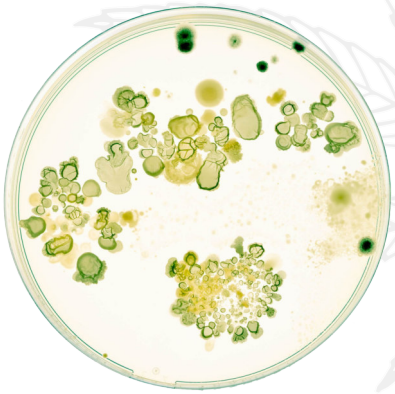
Influencing microbiological growth by:
- Temperature, humidity, and precipitation during pre- and post-harvest periods
- Adherence to basic hygiene measures (Kneifel et al., 2002; Bugno et al., 2006)
- Storage conditions (Busse et al., 2000)

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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