

CANNABIS APPROVED SOURCE AND SHELF STABILITY GUIDANCE

The Denver Department of Public Health & Environment's (DDPHE) Public Health Investigations Division (PHI) is responsible for enforcing Chapters 23 and 24 of the [Denver Revised Municipal Code](#) (D.R.M.C.) and the [Denver Retail Food Establishment Rules and Regulations](#), both of which have been established to preserve the health of consumers within the City and County of Denver. These rules and regulations oversee consumable products which are commercially manufactured and/or sold in Denver and ingested via non-smoking oral consumption (i.e. eating and/or drinking). The information below will assist with understanding how businesses can compliantly produce and/or sell cannabis products within the City and County of Denver.

***Note:** Commercial manufacturing of cannabis-infused and industrial hemp-derived products is an emerging industry. In turn, regulation of this industry is also emerging slowly as there is limited published research that addresses how pathogens grow in cannabis extractions and their derivatives. Until such information is available, it is the responsibility of PHI to utilize and apply existing food regulations to protect the health of consumers and to use existing research and food science to assess risks. Requirements may change as new information becomes available regarding the safety of cannabis extractions.*

PUBLIC HEALTH CONCERNS

The extraction process can be dangerous, and the final extract can be harmful to consume if the extraction is not performed properly. Solvent-based extractions must be conducted using a closed-loop system with an approved solvent and the system must be permitted by the Denver Fire Department if the extraction occurs within Denver. Verify compliance with both the Colorado Department of Public Health and Environment (CDPHE) and the Marijuana Enforcement Division (MED) for extractions taking place outside of Denver.

Any ingestible cannabis or hemp-derived products for non-smoking oral consumption sold to the public at retail, or sold wholesale to another business, are required to be from an approved source (see next section for additional information). Some cannabis products may require temperature control if not inherently shelf stable. The greatest public health concerns associated with cannabis extractions, infusions, and industrial hemp are approved source, shelf stability, and temperature control when not shelf stable. Therefore, these concerns are the primary focus for PHI.

APPROVED SOURCE

What qualifies as an approved source?

To be considered an approved source in Denver, all foods, and their ingredients, must come from a licensed and regulated food business. These ingredients might include hemp,

cannabis, chocolate, gelatin, etc. DDPHE recognizes [CDPHE's approved source list](#) of Colorado manufacturers as well as [licensed Marijuana Infused Products Facilities \(MIPs\)](#) as approved sources.

Hemp-derived food product manufacturers located outside of Colorado must meet approved source standards to be considered an approved source in Denver. Both DDPHE and CDPHE maintain the policy that hemp sourced outside the state shall utilize parts of the hemp plant that originate from a cultivator operating under a regulated industrial hemp program which applies safe consumption criteria. To be considered an approved source, product must come from a licensed and inspected food-grade facility. Visit CDPHE's [Hemp in Food website](#) for more information.

Required Registration/Licensing for Non-marijuana Manufacturers

Colorado hemp product manufacturers must register with CDPHE to be considered an approved source. Registration with CDPHE is also required if the business takes possession of the product being sold, even if the business only stores, packages, or brokers sales. Currently, there is no specific hemp product manufacturer registration for Denver, only a licensing requirement.

If located in Denver, a business producing product that will be sold to another business for retail sales needs a [Denver wholesale food license](#), in addition to the [wholesale registration with CDPHE](#). Denver retail cannabis businesses that sell potentially hazardous foods require a [Denver retail food establishment license](#) when selling at a brick-and-mortar location, or a [Denver temporary retail food establishment license](#) when selling at a temporary event, such as a festival or farmer's market. MED licensed facilities selling marijuana products are not subject to CDPHE registration or Denver wholesale food licensing. MED licensed facilities should ensure all ingredients are obtained from approved sources, including hemp derived ingredients.

SHELF STABILITY

All cannabis extractions, concentrates, and infusions intended for non-smoking oral consumption are considered a potentially hazardous food. Therefore, they must be refrigerated at 41° F or below, unless the business can provide PHI with documentation (upon request), that indicates the product meets the criteria of being shelf stable. Shelf stability takes place when a control step performed during production limits the formation of *Clostridium botulinum*.

What is Clostridium botulinum?

Clostridium botulinum (*C. botulinum*) is a bacterium whose spores are present on plant material and in soil. Spores are present in many plant material extractions and can survive cooking/pasteurization temperatures. These spores can spontaneously germinate (grow into bacteria) given the right conditions/substrate. The bacteria can produce a powerful toxin which can cause severe illness and even death.

Products of concern

Cannabis extractions and concentrates intended for non-smoking oral consumption (i.e. eating and/or drinking) including, but not limited to infused oils, butters, honey, tinctures, and beverages.

What are the known controls for preventing *C. botulinum* toxin formation?

- Irradiating plant material destroys the spores and bacteria, preventing toxin formation.
- Refrigerating the plant material extractions/concentrates and derivatives at 41°F or below prevents the growth of existing *C. botulinum* spores.
 - *Please note that if a cannabis extraction, concentrate, or infusion has been continuously refrigerated and is then added as an ingredient into baked goods that have low water activity, such as most hard candies, cookies, and brownies, these baked products are considered shelf stable.*
- Immediate infusion of extracted cannabis concentrates into a 190/200-proof alcohol with no additional ingredients (including flavorings or additives) prevents the growth of *C. botulinum* spores provided the tincture is homogenous. Homogenous 190/200-proof alcohol tinctures are safe to store outside of refrigerated temperatures.
- There may be other effective controls to prevent growth of *C. botulinum* toxin, such as destruction of spores by heating to very high temperatures under pressure for a certain period of time, but no known research establishes the thresholds for these controls in cannabis derivatives.
 - *Note: A process authority may be able to provide evidence of a shelf-stable product based on scientific principles.*

Which cannabis infused foods can be stored at room temperature?

The Denver Rules and Regulations Governing Food Establishments, as well as state and federal regulations, allow only non-potentially hazardous foods to be stored indefinitely at room temperature. To be considered non-potentially hazardous, a cannabis-infused food must meet the following criteria:

- The cannabis extraction and/or infused ingredient must be handled properly, as described in this memo prior to being used as an ingredient.
- The qualities of the food (water activity “aw” and/or acidity “pH”) must be such that the food will not support rapid growth of microorganisms outside refrigerated temperatures. Acidity and/or water activity testing shall be conducted by an accredited laboratory, 3-samples from separate batches shall be tested, and all samples shall meet the criteria for a non-TCS (time/temperature control for safety) food as described in Tables A and B of the [2013 FDA Food Code](#).
- The characteristics of the food shall not create an anaerobic environment for spores to grow, unless spores have been destroyed through irradiation or another approved process, such as an adequate heat step. Oily foods such as salad dressings, sauces, olive oils, glycerin/glycerol-based products, etc. must be stored at refrigerated temperatures unless spores have been destroyed.

Thermal Heat Step Control Measure:

- An adequate heat step for destruction of bacterial spores must clearly be established above the line in the “z-range” on the thermal death time chart (see below). Documentation may be requested.

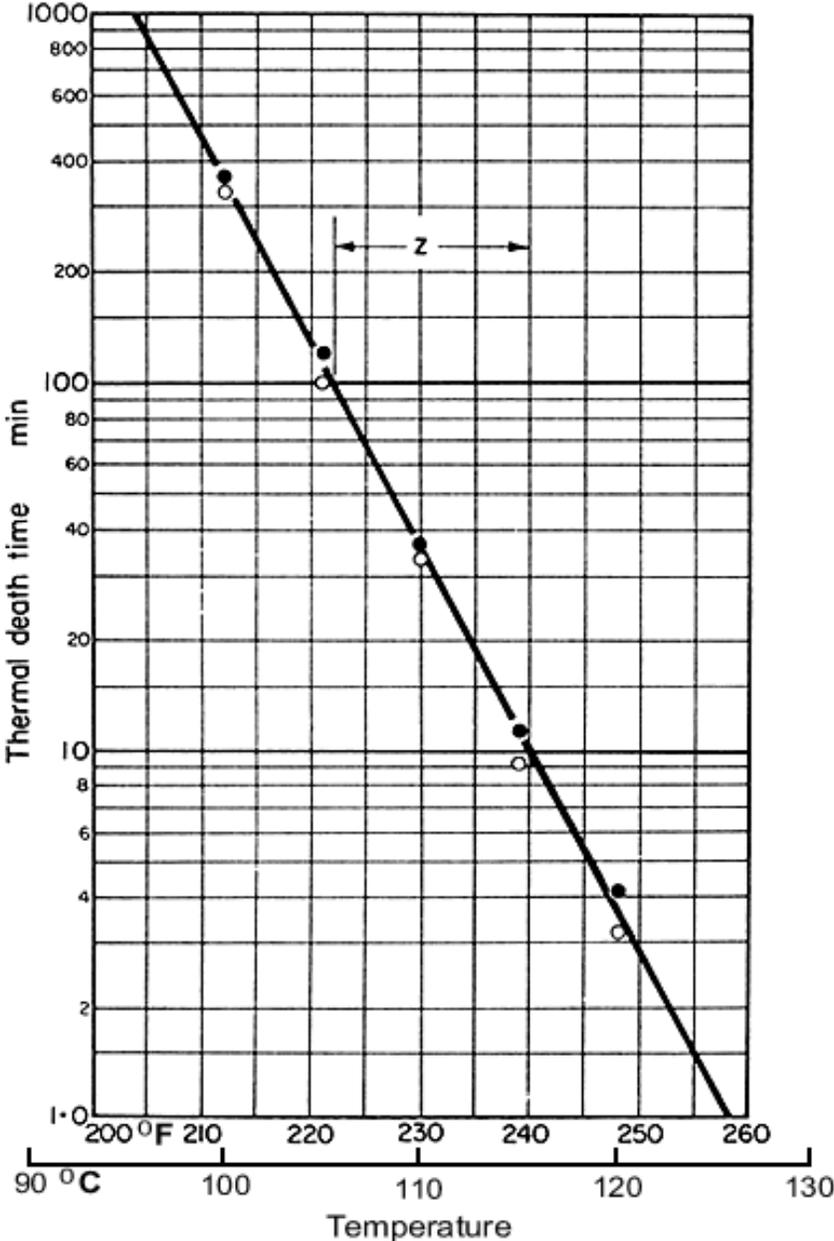


Figure 6.4. Thermal death time curve for *Clostridium botulinum*. Based on research results from the American Can Company

Approved Source and Shelf Stability Criteria

The following items shall be completed, and maintained onsite, to ensure all cannabis products being produced and/or sold are from an approved source and/or are shelf stable.

- Copies of all applicable licenses from required agencies, including but not limited to:
 - o CDPHE Wholesale Registration
 - o Denver Wholesale License
 - o Denver Retail Food License
 - o Department of Agriculture License for industrial hemp products
- Complete list of products with product description
- Complete list of other ingredients and ingredient manufacturers
 - o Manufacturers of other ingredients shall meet approved source criteria
- In-house extraction standard operating procedures (SOPs)
- Evidence of control measures to eliminate *C. botulinum*, such as time/temperature logs of heat step
- Invoices of plant material/documentation of source plant material

PHI will no longer issue shelf stability approval letters deeming cannabis products as non-potentially hazardous. Instead, businesses will need to complete a Shelf Stability Affidavit. DDPHE will continue to offer guidance to the cannabis industry with a focus on food safety education. Our team of cannabis subject-matter experts are available to assist with approved source and shelf stability questions and provide guidance to operators seeking clarity on this topic.

Please contact PHI at phicomments@denvergov.org with questions.

DEFINITIONS

Approved Source: Foods and ingredients that come from a licensed and regulated food business.

Colorado Department of Public Health and Environment (CDPHE): The Colorado State Health Department.

Denver Department of Public Health & Environment (DDPHE): The City and County of Denver Health Department.

Homogeneity: Refers to how evenly distributed the cannabis extract is through a product. For example, if 10% of the infused portion of the cannabis product contains less than 20% of the total THC contained in the product, it is homogenous. Homogeneity allows users assurance that they are consuming a consistently prepared edible.

Industrial Hemp: The plant of the genus *Cannabis* or any part of the plant, whether growing or not, with a delta-9-tetrahydrocannabinol concentration that does not exceed 0.3% on a dry weight basis of any part of the plant of the genus *Cannabis*.

Marijuana Enforcement Division (MED): The regulatory body tasked with licensing and regulating the Medical and Retail Marijuana industries in Colorado.

Non-potentially Hazardous Foods: A food that does not require time/temperature control for safety to limit pathogenic microorganism growth or toxin formation.

Potentially Hazardous Foods (PHF): A food that requires time/temperature control for safety to limit pathogenic microorganism growth or toxin formation. This includes a food of plant origin that is heat-treated. PHF is sometimes referred to as Time/Temperature Control for Safety (TCS).

Public Health Investigations (PHI): The division of DDPHE that regulates cannabis and cannabis-infused products for the City and County of Denver.

OTHER RESOURCES

Colorado Marijuana Enforcement Division

Website: <https://sbg.colorado.gov/marijuanaenforcement>

Phone: 303-866-3330

Email: christopher.poirier@state.co.us

CDPHE: Food Manufacturing and Storage

Website: www.cdphe.colorado.gov/food-manufacturing-and-storage

Phone: 303-692-3645, option 2

Email: cdphe_mfgfd@state.co.us

CDPHE: Hemp

Website: www.cdphe.colorado.gov/hemp-food

Phone: 303-692-3645, option 2

Email: cdphe.hemp.dehs@state.co.us

Denver Fire Department

Website: www.denvergov.org/Government/Departments/Fire-Department/Permits-Licensing/Fire-Safety-Operational-Permits

Phone: 720-913-3474

Email: denfpb@denvergov.org