

Special Concerns Associated with Cannabis Extractions, Concentrations, Infusions, And Infused Food

The Public Health Inspections Division (PHI) of the Denver Department of Public Health and Environment (DDPHE) is responsible for enforcing regulations that preserve the health of consumers in Denver. PHI enforces the Denver Rules and Regulations Governing Food Establishments to regulate all food/products which are commercially manufactured and/or sold in Denver and that are ingested via non-smoking oral consumption (i.e. eating, drinking). Please visit www.denvergov.org/phi for more information or to view the Regulations.

Commercial manufacturing of cannabis-infused products is an emerging industry, and regulation of this industry is a new area of regulation. There is no known 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 enforce existing food regulations to protect the health of consumers and to use existing research and food science to assess the risks of foods. Requirements may change as new information becomes available regarding the safety of cannabis extractions.

What are the public health concerns associated with cannabis extractions and infusions?

The extraction process can be dangerous if not performed properly, and the final extract can be harmful to consume if the extraction is not performed properly. All extractions must be conducted using a closed loop system with an approved solvent, and in Denver the system must be permitted by the Fire Department. Refer to the State's Marijuana Rules for further information about extraction requirements.

Clostridium botulinum is a bacteria 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 or death.

What are the products of concern?

Affected products include:

- cannabis extractions and concentrates intended for non-smoking oral consumption (i.e. eating, drinking)
- most infusions made from these extractions, such as infused oils, butters, honey, etc.
- many foods that have such infusions/extractions as an ingredient

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 less 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 a low water activity, such as most cookies and brownies, these baked products are considered shelf-stable.)
- Immediate infusion of extracted cannabis concentrate into a 190/200 proof alcohol with no additional ingredients (including flavorings or other 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.

What is required for storage of extractions and infusions?

All cannabis extractions, concentrates, and infusions intended for non-smoking oral consumption must be refrigerated at temperatures of 41°F unless otherwise approved by PHI. Approvals are based on a review of written procedures that are followed to make the product; the use of control measures described above; and any other scientific evidence submitted by the manufacturer from a certified laboratory or process authority that demonstrates the safety of the product in question.

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. In order 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 as described in this memo prior to being used as an ingredient.
- The qualities of the food (water activity and/or pH) must be such that the food will not support rapid growth of microorganisms outside refrigerated temperatures. pH and/or water activity testing must be conducted by an accredited laboratory; three samples from separate batches must be tested; and all samples must meet the criteria for a non-potentially hazardous food as described in Tables A and B of the 2013 *FDA Food Code*.
- The characteristics of the food must not provide an anaerobic environment for spores to grow (unless spores have been destroyed through irradiation or another process approved by the Department). Oily foods such as salad dressings, sauces, olive oils, glycerine/glycerol based products, etc. or reduced oxygen packaged foods must be stored at refrigerated temperatures unless spores have been destroyed and approval has been provided by the Department.

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What is required for manufacturers and retailers of cannabis extractions, infusions, and infused foods?

Manufacturers and retailers should ensure all extractions are conducted using an approved solvent in a closed-loop system that is licensed by the Fire Department. Products that have been extracted using an unapproved system are considered unwholesome and should be disposed of.

All products intended for non-smoking oral consumption must meet the criteria herein to control for growth of *C. botulinum* and other pathogens unless a written plan to use another control has been submitted and approved by the Department. Selling foods that have not been handled as described may result in enforcement action such as issuing of orders, administrative citations (fines), court summons, or action against a license.

For questions, please contact Public Health Investigations at 720-913-1311 or phicomments@denvergov.org.

Visit us online at www.denvergov.org/phi or on Facebook at Denver Public Health Inspections.

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