

Concerns Associated with Cannabis Extractions, Concentrations, Infusions, and Infused Foods

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 information is available, it is responsibility of the Tennessee Department of Agriculture (TDA) 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.

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 extractions is not performed properly. All extractions must be conducted using a closed loop system with an approved solvent.

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 of death.

What are the products of concern?

- Cannabis extractions and concentrates intended of oral consumption
- Most infusions made from these extractions, such as infused oils, butters, honey, etc.
- Many foods have such infusions/extractions as an ingredient

What are 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 41F or less prevents the growth of existing *C. botulinum* spores.
 - 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 (<.85), 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 oral consumption must be refrigerated at temperatures of 41°F unless otherwise approved by TDA. 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 Retail Food Store Sanitation regulations allow only non-Tme/temperature control for safety food (TCS) to be stored indefinitely at room temperature. In order to be considered non-TCS, a cannabis-infused food must meet the following criteria:

- 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. Samples must meet the criteria for non-TCS food as described in Tables A and B of the Retail Food Store Sanitation Regulations (pages 16 and 17).
- The characteristics of the foods must not provide an anaerobic environment for spores to grow (unless spores have been destroyed through irradiation or another process approved by TDA). 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 TDA.

For questions please contact the Food Safety Section at the Tennessee Department of Agriculture 615-837-5193.

Visit us on line at www.tn.gov/agriculture/consumers/food-safety.html