



# Cannabis Products Safety Education: Introduction

June 15, 2020

# UC DAVIS

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## FOOD SCIENCE AND TECHNOLOGY



Manufactured Cannabis Safety Branch (MCSB)

Cannabis Products  
Safety Education  
Contract

- Develop and Deliver Curriculum to MCSB Inspectors

A close-up photograph of a hand holding a pen, writing on a checklist in a notebook. The checklist has several items with checkboxes, some of which are already marked. The background is slightly blurred, showing more of the notebook and the hand.

# Session 1

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- Introduction to Zoom
- Comments from Zarha Ruiz, REHS
  - Inspection and Compliance Section Chief, Manufactured Cannabis Safety Branch
- Introduction to Instructors
- Outline of Course Objectives
- Overview of Cannabis Manufacturing Regulation
  - Food Safety Aspects



## Session 2 and 3

- Monday June 22 and 29
  - 1 to 2 pm
- Zoom
  - Same meeting number and password

You can move or hide



# UCDAVIS

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## FOOD SCIENCE AND TECHNOLOGY

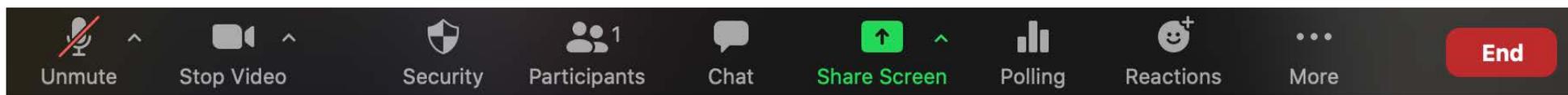


Cannabis Products  
Safety Education  
Contract

- Develop and Deliver Curriculum to MCSB Inspectors



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Participants



Participants (1)

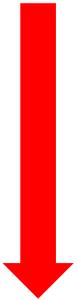


Linda J Harris (Host, me)



If your last name begins with the letter:

**A to H** – hit **YES**



If your last name begins with the letter:

**I to S** – hit **Go Faster**



yes



no



go slower



go faster



more



clear all

Invite

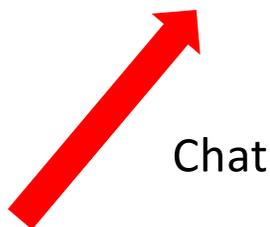
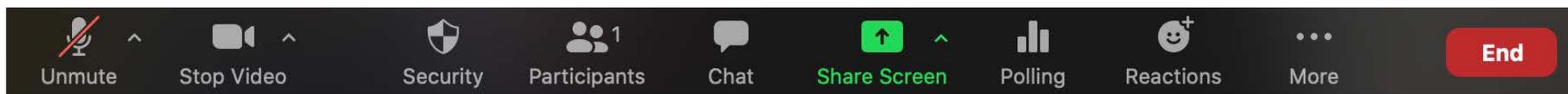
Mute All

Unmute All

More ▾



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Chat

# Chat will be monitored



Chat

From Me to **Everyone**:  
Hi everyone!

1:35 PM

If your last name begins with the letter:  
**T to Z** – Type something in Chat  
to everyone

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To: Everyone

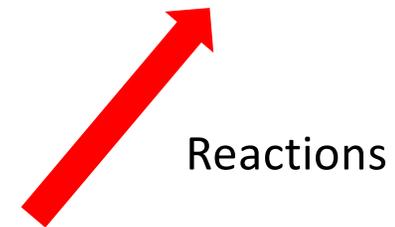
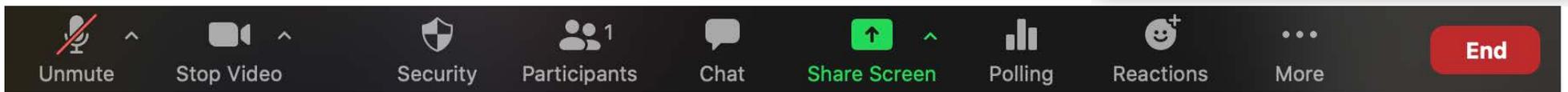
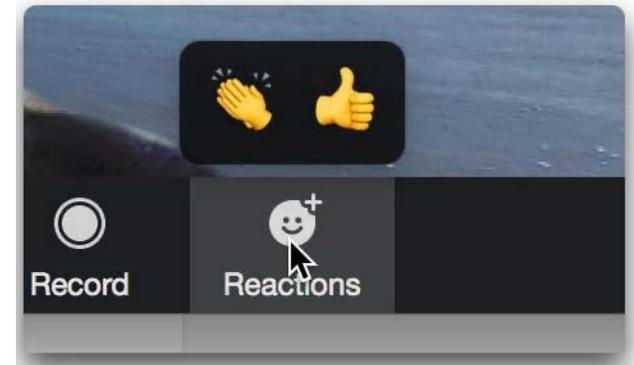


Type message here...

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Hover over bottom of Zoom screen



Reactions



### Upcoming Events

#### Calendar

No Upcoming Events

[See all »](#)

Research and Extension faculty at UC Davis, [Drs. Erin DiCaprio and Linda J. Harris](#), welcome you to the University of California Food Safety website. You can find resources including [events](#), [presentations](#), [publications](#) and [website links](#) related to the [safe production](#), [harvest](#) and [processing](#) of foods. The emphasis is microbial food safety from the [farm](#) to the [kitchen](#), with a special emphasis on [low moisture foods](#).



Linda J. Harris, PhD CFS



Erin DiCaprio, PhD



Nina Parkinson

# Instructors

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## Linda J. Harris, PhD CFS

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- Specialist in Cooperative Extension and Chair, Department of Food Science and Technology UC Davis
- Research program in microbial food safety
- Extension Training - regulatory
  - Implementation of Meat HACCP (mid 1990s) 9 CFR 417
  - Curriculum development for Juice HACCP 21 CFR 120
  - Better Process Control School 21 CFR 113 and 21 CFR 114
  - Lead Trainer for 21 CFR 117 (Preventive Controls Rule)
  - Lead Trainer for 21 CFR 112 (Produce Safety Rule)
  - FD 152 at UC Davis (FDA food processing course)
  - Getting Started in the Specialty Food Business



## Erin DiCaprio, PhD

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- Assistant Specialist in Cooperative Extension, Department of Food Science and Technology UC Davis
- Research program in microbial food safety (virology)
- Extension Training - regulatory
  - Better Process Control School 21 CFR 113 and 21 CFR 114
  - Lead Trainer for 21 CFR 117 (Preventive Controls Rule)
  - Lead Trainer for 21 CFR 112 (Produce Safety Rule)
  - FD 152 at UC Davis (FDA food processing course)
  - Getting Started in the Specialty Food Business



# Nina Parkinson

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- Director, UC Laboratory for Food Preservation
  - Laboratory support for the CA Botulism Control Program
    - Acidified low acid and low acid foods
- Extension Training - regulatory
  - Lead Instructor
    - HACCP: 21 CFR 120, 9 CFR 417
  - Better Process Control School 21 CFR 113 and 21 CFR 114
  - Good Manufacturing Practices

# Course objectives - edibles

- MCSB Inspectors will gain skills to allow for confident inspection of manufactured cannabis facilities and evaluation of quality control plans for a range of cannabis products
- This will include an understanding of
  - Principles behind good manufacturing practices and sanitation
  - Concepts of hazards and hazard analysis
  - Principles of food processing controls



# Definition

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- “Edible cannabis product”
  - Intended to be used, in whole or in part, for human consumption, including, but not limited to, chewing gum but excluding products set for in Division 15 (commencing with Section 32501) of the Food and Agricultural Code.
    - Milk and Milk Products Act of 1947
- An edible cannabis product is **not considered food**, as defined by Section 109935 of the Health and Safety Code, **or a drug**, as defined by Section 109925 of the Health and Safety Code.

# National/State Food Agencies Pertaining to Food

Federal Agency	Corresponding State Agency
US Food and Drug Administration (FDA) (Title 21)  Advisory through Pasteurized Milk Ordinance (FDA)	California Department of Public Health Food and Drug Branch (CDPH FDB) <i>Manufactured Cannabis Safety Branch</i> California Department of Food and Agriculture <b>Milk and Dairy Food Safety Branch</b>
US Department of Agriculture (USDA) (Title 9) Food Safety and Inspection Service (FSIS) Agricultural Marketing Service (AMS)	California Department of Food and Agriculture Meat Branch (USDA/FSIS) (Leafy Greens Marketing Agreement Audits)
Environmental Protection Agency (EPA) (Title 40)	California Environmental Protection Agency
US Food and Drug Administration (FDA) Food Code (advisory)	County Departments of Environmental Health (CDPH FDB is also advisory)
Many Others	Many Others

# Ingredients – Regulatory Authority

USDA-FSIS  
Meat Inspection  
Act 1906



Meats



Poultry

Amenable  
Species

In some cases CDFA Meat Poultry and Egg Safety Branch

# Meat or Meat-Containing Products

9 CFR 304, 308, 310, 320, 327, 381, 416 and 417

- Fresh and processed meat and poultry
- Raw products
  - containing 3% or more by weight of meat or poultry
- Cooked products
  - containing 2% or more of meat or poultry
- **Meat ingredients must be**
  - **Slaughtered under USDA-FSIS inspection**
  - Less likely CDFA
- **Manufacturing of meat-containing product**
  - **Under USDA-FSIS inspection**



# Ingredients – Regulatory Authority

USDA-FSIS  
Meat Inspection  
Act 1906



Meats



Poultry

Amenable  
Species

FDA

Food Drug and Cosmetic Act 1938  
Food Safety Modernization Act 2011



Oil/Oil seeds



Tree nuts, Fruits,  
Vegetables



Seafood



Cereals and  
Grains



Dairy



Additives/  
preservatives  
ingredients



Legumes



Juices



Interstate  
VS  
Intrastate

CDFA Milk and  
Dairy Food  
Safety Branch



Milk Products  
Products Resembling Milk Products

CA version of Pasteurized Milk Ordinance

# Preventive Controls for Human Foods

## 21 CFR 117

Subpart	Title
A	General Provisions, Definitions, Qualifications, Exemptions
B	Current Good Manufacturing Practice
C	Hazard Analysis and Risk Based Preventive Controls
D	Modified Requirements
E	Withdrawal of A Qualified Facility
F	Requirements Applying to Records That Must be Established and Maintained
G	Supply Chain Program

## Subpart B: Current Good Manufacturing Practices

Section	Title	CDPH MCSB
117.10	Personnel	40246
117.20	Plant and Grounds	40240
117.35	Sanitary operations	40240
117.37	Sanitary facilities and controls	40240
117.40	Equipment and utensils	40243
117.80	Processes and controls	40253 (Also draws on 117 Subpart C)
117.93	Warehousing and distribution	
117.95	Holding and distribution of by-products for animal food (21 CFR 507)	
117.110	Defect action levels	

# FDA Product-Specific Regulations

- Seafood or seafood-containing products
  - 21 CFR 123
  - Seafood **Hazard Analysis and Critical Control Points**
- Juices
  - 21 CFR 120
  - Juice **Hazard Analysis and Critical Control Points**
- Low acid and Acidified low acid foods (shelf stable)
  - 21 CFR 113 and 114 California pH control or botulism control program



## §40300. Prohibited Products



(a) Alcoholic beverages



(b) With prohibited additive (e.g., nicotine and caffeine)

\*Does not include natural caffeine – coffee, tea, chocolate

# Allowable Products

- Naturally caffeinated



# §40300. Prohibited Products

## (c) Temperature controlled for safety (TCS) foods

- Must be held  $\leq 41^{\circ}\text{F}$

Many types of foods are refrigerated for quality and not for safety



# Allowable Products

- Juice or beverages processed in accordance to §40270
- Infused butter as permitted by subsection (g)



# §40300. Prohibited Products

(d) Thermally-processed low-acid

- Under 21 CFR 113



• (e) Acidified cannabis product

- Under 21 CFR 114



# Allowable Products

- Low water activity products (<0.85)
  - E.g., jams/jellies (typical water activity <0.70)
- Others (needs approval):
  - small amounts of low acid (some dressings)
- Naturally acidic
  - E.g., peaches, apples
- Traditional fermented
  - E.g., sauerkraut, fermented dill



## §40300. Prohibited Products

### (f) Juice

- Not shelf stable OR
- Not processed by §40270

# Allowable Products

- Shelf stable juices
- Processed under §40270: Cannabis juice, and cannabis-infused juice or beverages
  - Written juice HACCP plan in accordance with
    - 21 CFR 120 Subpart A 120.8 and
    - Subpart B section 120.24

## Definitions – 21 CFR 120

- *Juice* means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrates of such liquid or puree.
- *Shelf-stable product* means a product that is hermetically sealed and, when stored at room temperature, should not demonstrate any microbial growth.

# Preventive Controls for Human Foods

## 21 CFR 120 Subpart A – General Provisions

	Title
120.1/3	Applicability and Definitions
120.5	Current good manufacturing practices
120.6	Sanitation standard operating procedures
120.7	Hazard analysis
<b>120.8</b>	<b>Hazard Analysis and Critical Control Point (HACCP)</b>
120.9	Legal basis
120.10	Corrective actions
120.11	Verification and validation
120.12	Records
120.13	Training

# Preventive Controls for Human Foods

## 21 CFR 120 Subpart B – Pathogen Reduction

	Title
120.20	General
120.24	Process controls
120.25	Process verification for certain processors

120.24 (2) A juice processor using a single thermal processing step sufficient to achieve **shelf-stability** of the juice or a thermal concentration process that includes thermal treatment of all ingredients, provided that the processor includes a copy of the thermal process used to achieve shelf-stability or concentration in its written hazard analysis required by **120.7**.

## §40300. Prohibited Products

(g) Dairy products of any kind (§26001(t))

Food and Agricultural Code Division 15

§32501 Milk and Milk Products Act of 1947

Allowable: Infused butter



## §40300. Prohibited Products

(h) Meat products other than dried meat processed by §40272

(i) Seafood products of any kind



# §40300 Prohibited Products

USDA-FSIS  
Meat Inspection  
Act 1906



Meats



Poultry

Amenable  
Species

(h) Meat products other than dried meat processed by §40272

§40272 Dried Meat Processing  
FSIS Compliance Guideline for  
Meat and Poultry Jerky  
Produced by Small and Very  
Small Establishments:  
2014 Compliance Guideline



Meat ingredient from a “commercially-available source”

## §40300. Prohibited Products

(j) Application of cannabinoid concentrate or extract to a commercially available candy or snack food without further processing.

Can be used as ingredient as long as not recognizable as original or noted on ingredient list.

# §40300. Prohibited Products

Case-by-case basis:

(k) attractive to children

(l) easily confused with commercially available food (nonscannabis)

(m) in shape of or imprinted with human, animal, insect, or fruit



# Article 3. Good Manufacturing Practices

- §40230 Manufacturing Practices Definitions
- §40235 Quality Control Program
- §40240 Grounds, Building, and Manufacturing Premises
- §40243 Equipment and Utensils
- §40246 Personnel
- §40248 Cannabis Product Components
- §40250 Manufacturing Processes and Procedures
- §40253 Product **Quality** Plan
- §40255 Master Manufacturing Protocol
- §40258 Batch Production Record

# Article 6. Other Responsibilities

- §40275 Standard Operating Procedures
  - (4) Policies and procedures developed in accordance with Article 3 (GMPs)

# Article 6. Other Responsibilities

- §40280 Training Program – shall implement
  - (1) Within 30 days of the start of employment for all personnel covering
    - (A) Health and safety hazards
    - (E) Record Keeping Requirements
  
  - (2) Manufacturing and production personnel (prior to engaging + annually)
    - (A) Overview of process and SOPs
    - (B) Quality control procedures
    - (C) Product quality plans (§40253)
    - (F) Cleaning and maintenance requirements
  - (3) All personnel who prepare, handle, or package edible products  
Complete California food handler certificate course

## Article 6. Other Responsibilities

- 40297. Recalls
- Shall establish and implement written procedures for recalling cannabis products

# Homework for next week

- Identify food product examples on which to build course materials
  - Shelf stable carbonated and uncarbonated beverages
  - Refrigerated beverage
  - Butter
  - Jerky
  - Chocolate, coffee or tea

