

NAVIGATING INDUSTRIAL HEMP REGULATIONS IN COLORADO

PRESENTED BY THUY VU
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REGULATORY AFFAIRS**
**HAMMER ENTERPRISES
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FOOD SAFETY SUMMIT
ROSEMONT, IL
MAY 9, 2019

HAMMER ENTERPRISES

www.hammerenterprises.com

HAMMER ENTERPRISES

- EST NOVEMBER 2015
- VERTICALLY-INTEGRATED INDUSTRIAL HEMP OPERATION IN COLORADO
- IN AUGUST 2017, HE APPLIED FOR THE FIRST AIR POLLUTION EMISSIONS NOTICE (APEN) FOR THE CANNABIS INDUSTRY IN COLORADO AND THE NATION. HE WORKED WITH CDPHE AIR POLLUTION CONTROL DIVISION AND OTHER STATE AGENCIES TO CONTACT OTHER INDUSTRIAL HEMP AND MARIJUANA OPERATIONS ABOUT THE REQUIREMENT.
- HE SUCCESSFULLY PETITIONED FOR REZONING APPROVAL OF THE FIRST INDUSTRIAL HEMP EXTRACTION OPERATION IN JEFFERSON COUNTY, COLORADO IN OCTOBER 2017.
- HAMMER ENTERPRISES IS THE FIRST CANNABIS COMPANY TO BE AWARDED THE BRONZE ENVIRONMENTAL ACHIEVEMENT AWARD BY CDPHE'S ENVIRONMENTAL LEADERSHIP PROGRAM.



BACKGROUND

- 2010-2015: Lead foodborne illness, outbreak, and marijuana investigator for Denver Department of Public Health and Environment, Public Health Inspections Division.
- 2014 Rocky Mountain Food Safety Conference: Food Safety Regulation of Marijuana Products in Denver
- The FIRST Environmental Health Investigator to specialize in marijuana operations, spearheading inspections, investigations, and enforcement of the Denver marijuana industry, implementing the FIRST 5 food safety recalls of marijuana infused products and the FIRST foodborne illness outbreak of a licensed recreational marijuana operation in 2014.
 - Cease & desist orders for several operations not equipped for food handling
 - Product recall and disposals for vacuum packaged product, extracted oils and infused products treated as non-PHF without demonstration of shelf-stability
 - Summons for 3 manufacturers for incomplete recalls
 - Civil penalties for repeat violations
 - Administrative Holds on plants treated with unapproved pesticides
 - Product recalls and disposal of concentrates and infused edibles derived from plants tainted with unapproved pesticides
- Bachelor of Science in Microbiology from the University of Rochester in Rochester, NY.
- Certifications:
 - Preventative Controls Qualified Individual
 - National Restaurant Association ServSafe Food Protection Manager, ServSafe Instructor, ServSafe Proctor
 - 3M Respirator Fit Tester



County Fair Chocolate Scare

A Foodborne Outbreak Investigation Case Study

Developed by the
**Colorado Integrated Food Safety
Center of Excellence**

INSTRUCTOR



Marijuana Edibles: Food safety risks and outbreak investigation resources for public health agencies

Public Health in the Rockies

August 2018

The Integrated Food Safety Centers of Excellence (CoEs) were established under the Food Safety Modernization Act (FSMA) to:

“... serve as resources for federal, state, and local public health professionals to respond to foodborne illness outbreaks.”

“... provide assistance to other regional, state, and local departments of health ...”



BACKGROUND

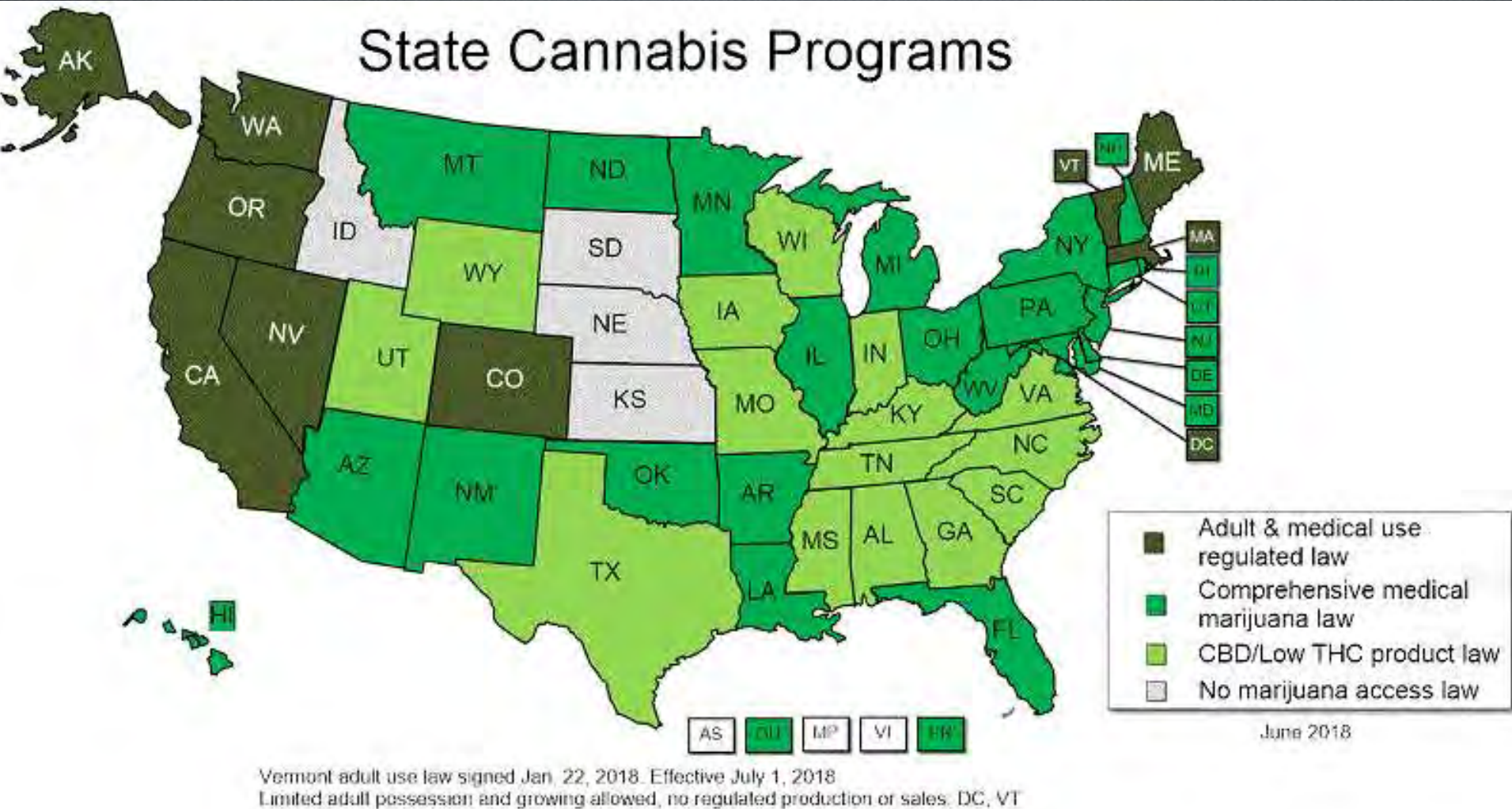
- 5+ years experience in the private marijuana & industrial hemp industries, specializing in cannabis extraction & refinement processes, concentrate & infused-products manufacturing, inventory tracking & compliance, new product development, and regulation of these industries.
- Oversaw the product research, development, and launching of Leafs by Snoop in 2015, the first commercial celebrity cannabis product line.
- **Consulted with Denver Fire Department, resulting in the hazardous location classification requirements for Class I Division I and Class I Division 2 Extraction Rooms in the City and County of Denver in 2015, helping set the precedent for the rest of the nation.**
- **Successfully petitioned for rezoning approval of the first industrial hemp extraction operation in Jefferson County, Colorado in October 2017.**



BACKGROUND

- **Presented at:**
 - AFDO, WAFDO, AFDOSS
 - Rocky Mountain Food Safety Conference (RMFSC)
 - Public Health Nurses Association of Colorado (PHNAC)
 - Northwest Food Processors Association (NFPA)
 - American Chemical Society (ACS)
 - Colorado Chapter of the International Code Council (ICC)
 - Rocky Mountain Chapter of the Society of Fire Protection Engineers (SFPE).
 - American Veterinary Medical Association (AVMA)
- **Conducted cannabis extraction training for:**
 - Denver Department of Public Health & Environment
 - Denver Public Health
 - Colorado Department of Public Health & Environment
 - Alaska Div. of Env. Health Food Safety & Sanitation Program
 - Hawaii Department of Health Sanitation Food and Drug Branch
 - Louisiana Department of Health
 - Sheridan Police Department
- **Consults on cannabis extraction operations with:**
 - Denver Fire Department
 - Colorado Department of Public Health & Environment (Industrial Hemp Program- July 2017)
 - Oakland Fire Department
 - Sheridan Police Department
 - Michigan Bureau of Fire Services Bureau of Medical Marijuana Regulation
 - Monterey Fire Department

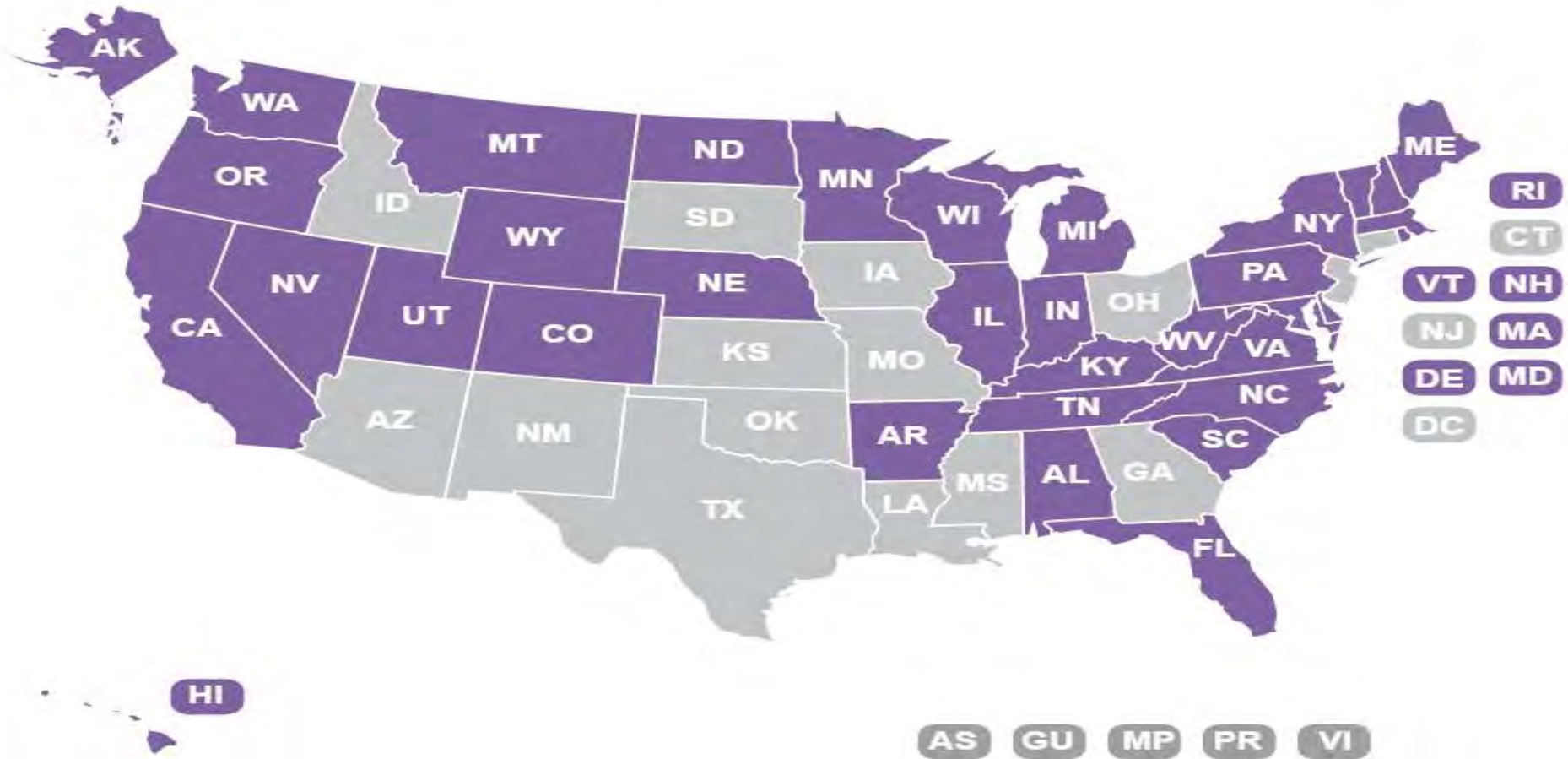
STATES AND US TERRITORIES WITH CANNABIS PROGRAMS (2018)



STATES AND US TERRITORIES WITH INDUSTRIAL HEMP PROGRAMS (2018)

Allows cultivation of hemp for commercial, research or pilot programs

Does not allow cultivation of hemp.



MARIJUANA/MARIHUANA DEFINED

ACCORDING TO 21 USCS § 802 [TITLE 21. FOOD AND DRUGS; CHAPTER 13. DRUG ABUSE PREVENTION AND CONTROL, CONTROL AND ENFORCEMENT, INTRODUCTORY PROVISIONS], MARIHUANA MEANS “ALL PARTS OF THE PLANT *CANNABIS SATIVA L.*, WHETHER GROWING OR NOT; THE SEEDS THEREOF; THE RESIN EXTRACTED FROM ANY PART OF SUCH PLANT; AND EVERY COMPOUND, MANUFACTURE, SALT, DERIVATIVE, MIXTURE, OR PREPARATION OF SUCH PLANT, ITS SEEDS OR RESIN. SUCH TERM DOES NOT INCLUDE THE MATURE STALKS OF SUCH PLANT, FIBER PRODUCED FROM SUCH STALKS, OIL OR CAKE MADE FROM THE SEEDS OF SUCH PLANT, ANY OTHER COMPOUND, MANUFACTURE, SALT, DERIVATIVE, MIXTURE, OR PREPARATION OF SUCH MATURE STALKS (EXCEPT THE RESIN EXTRACTED THEREFROM), FIBER, OIL, OR CAKE, OR THE STERILIZED SEED OF SUCH PLANT WHICH IS INCAPABLE OF GERMINATION.”



INDUSTRIAL HEMP DEFINED

AMENDMENT 64 TO THE COLORADO CONSTITUTION AND THE COLORADO REVISED STATUTES (C.R.S.), §35-61-101(7), DEFINES INDUSTRIAL HEMP AS
“A PLANT OF THE GENUS *CANNABIS* AND ANY PART OF THE PLANT, WHETHER GROWING OR NOT, CONTAINING A DELTA-9 TETRAHYDROCANNABINOL (THC) CONCENTRATION OF NO MORE THAN THREE-TENTHS OF ONE PERCENT (0.3%) ON A DRY WEIGHT BASIS.”



COLORADO DEPARTMENT OF AGRICULTURE



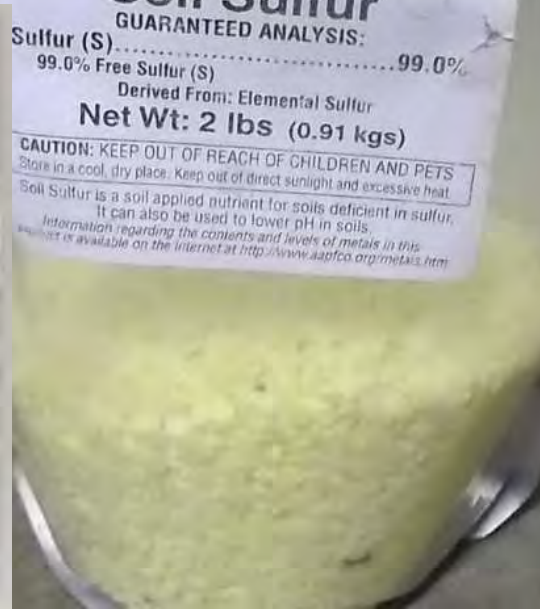
- REGULATES THE REGISTRATION AND CULTIVATION OF INDUSTRIAL HEMP.
- CDA APPROVED CERTIFIED SEED PROGRAM
- ALL PLANTS WITHIN THE REGISTERED LAND AREA (RLA) MUST MEASURE BELOW 0.3% THC.
 - 0.3-1.0 % THC = CIVIL PENALTY OR REQUEST WAIVER IF MATERIAL IS DESTROYED ONSITE, NOT USED FOR HUMAN CONSUMPTION, AND DOES NOT ENTER THE STREAM OF COMMERCE.
 - >1.0 % THC = CIVIL PENALTY
 - NON-COMPLIANCE IS SUBJECT TO CRIMINAL PENALTY.

COLORADO DEPARTMENT OF AGRICULTURE



- ADOPTED RULES SETTING CRITERIA FOR USE OF ALLOWABLE PESTICIDES IN CANNABIS CULTIVATION IN ACCORDANCE WITH THE COLORADO PESTICIDE APPLICATOR'S ACT.
- 40 CFR PART **170: EPA's AGRICULTURAL WORKER PROTECTION STANDARDS (WPS)** REQUIRES OWNERS AND EMPLOYERS OF AGRICULTURAL ESTABLISHMENTS:
 - PROVIDE PPE TO WORKERS AND HANDLERS FROM POTENTIAL PESTICIDE EXPOSURES;
 - PROVIDE TRAINING ON SAFE USE AND APPLICATION OF PESTICIDES;
 - PROVIDE TRAINING ON HOW TO AVOID EXPOSURES TO PESTICIDES; AND
 - IDENTIFY PESTICIDE EXPOSURE SYMPTOMS AND HOW TO RESPOND AND MANAGE EXPOSURES TO PESTICIDES IF THEY OCCUR.

The collage displays four agricultural product labels. The top-left label is for Eagle 20EW Specialty Fungicide by Dow AgroSciences, featuring a box and two jugs. The top-right label is for Mallet 75 WSP Insecticide by TheLandscapeStore.com. The bottom-left label is for Merit 2F Insecticide by Bayer. The bottom-right label is for Soil Sulfur by Mulsart.





PESTS AND FUNGAL INFECTIONS

- YEAST & MOLD
- POWDERY MILDEW
- BUD ROT
- MYCOTOXINS
(AFLATOXINS & OCHRATOXINS)
- BLACK MOLD
- SPIDER MITES
- RUST MITES
- APHIDS
- THRIPS

COLORADO DEPARTMENT OF PUBLIC HEALTH & ENVIRONMENT DIVISION OF ENVIRONMENTAL HEALTH & SUSTAINABILITY

IN JULY 2017, THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT (CDPHE) DIVISION OF ENVIRONMENTAL HEALTH AND SUSTAINABILITY ANNOUNCED A **NEW INDUSTRIAL HEMP POLICY RECOGNIZING ALL PARTS OF THE INDUSTRIAL HEMP PLANT, INCLUDING CANNABIDIOL (CBD), AS A FOOD INGREDIENT.** CDPHE'S INDUSTRIAL HEMP POLICY IS THE FIRST OF ITS KIND IN THE NATION AND IS THE MOST PROGRESSIVE PROGRAM APPLYING CURRENT GOOD MANUFACTURING PRACTICES TO A NEW FOOD INGREDIENT AND FOR A NEW EMERGING INDUSTRY.

HAMMER ENTERPRISES INTEGRATED SOLUTIONS PLAYED A PIVOTAL ROLE IN THE SUCCESSFUL IMPLEMENTATION OF CDPHE'S INDUSTRIAL HEMP PROGRAM. HAMMER ENTERPRISES SERVES AS THE FIRST AND ONLY VERTICALLY INTEGRATED INDUSTRIAL HEMP COMPANY THAT HAS COMMITTED TO A PROFESSIONAL PARTNERSHIP WITH CDPHE AS WELL AS OTHER GOVERNMENT AND REGULATORY AGENCIES IN EFFORTS TO ADVOCATE FOR INFORMED, BALANCED, AND FAIR REGULATIONS FOR THE NEW INDUSTRY.



CONDITIONS OF CDPHE'S INDUSTRIAL HEMP POLICY

- ALL PARTS OF THE HEMP PLANT UTILIZED IN FOOD MUST COME FROM A STATE THAT HAS AN ESTABLISHED AND APPROVED INDUSTRIAL HEMP PROGRAM OR A COUNTRY THAT INSPECTS OR REGULATES HEMP UNDER A **FOOD SAFETY PROGRAM OR EQUIVALENT CRITERIA TO ENSURE SAFETY FOR HUMAN CONSUMPTION.**
- THE IH PRODUCER/GROWER MUST BE IN GOOD STANDING AND IN COMPLIANCE WITH THE GOVERNING LAWS WITHIN THE STATE OR COUNTRY OF ORIGIN.

CONDITIONS OF CDPHE'S INDUSTRIAL HEMP POLICY

- THE IH MUST CONFORM TO THE STANDARD OF IDENTITY ESTABLISHED IN C.R.S., §35-61-101(7) OF NO MORE THAN THREE-TENTHS OF ONE PERCENT DELTA-9 TETRAHYDROCANNABINOL (THC).
- THE USE OF OTHER PARTS OF THE IH PLANT OTHER THAN SEED AND ITS DERIVATIVES (SEED MEAL, FLOUR, AND OIL) SHALL HAVE LAB TEST RESULTS INDICATING THE LEVELS OF THC WITHIN THE DERIVATIVES ARE NOT ABOVE THE ALLOWABLE LIMIT OF THREE-TENTHS OF ONE PERCENT THC.
- THE PRODUCER MUST BE ABLE TO DOCUMENT THAT THE FINISHED PRODUCT DOES NOT CONTAIN MORE THAN THREE-TENTHS OF ONE PERCENT THC.

CONDITIONS OF CDPHE'S INDUSTRIAL HEMP POLICY

- THE PRODUCT MUST BE LABELED IN CONFORMANCE WITH STATE AND FEDERAL LABELING LAWS, INCLUDING:
 - CLEARLY IDENTIFY HEMP AS AN INGREDIENT;
 - CLEARLY IDENTIFY CBD AND THE AMOUNT OF CBD IF ADDED AS AN ISOLATE;
 - INCLUDE THE STATEMENT, “**FDA** HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY”; AND
 - DO NOT STATE ANY HEALTH OR BENEFIT CLAIMS.



CDPHE MANUFACTURED FOODS REGISTRATION IS REQUIRED FOR INDUSTRIAL HEMP OPERATIONS TO BE LISTED AS AN APPROVED SOURCE

Primary and Secondary
Extraction Processing

Food & Cosmetics
Manufacturers and
Processors

Re-packers

Brand Owners

Warehouse and Storage
Facilities

Retailers

Any operation
manufacturing,
processing, handling, and
storing industrial hemp
and its derivatives for
human consumption.

APPROVED SOLVENT & SOLVENTLESS EXTRACTION IN COLORADO

APPROVED SOLVENTS FOR MARIJUANA

- SOLVENTLESS EXTRACTIONS
 - DRY SIEVE/SIFT
 - DRY ICE
 - COLD/HOT WATER EXTRACTION
 - HEAT PRESS (HYDRAULIC/PNEUMATIC/MANUAL)
- NON-HYDROCARBON SOLVENT EXTRACTIONS
 - ETHYL ALCOHOL/ETHANOL
 - ISOPROPYL ALCOHOL/ISOPROPANOL
 - ACETONE
 - SUPERCRITICAL/SUBCRITICAL CO₂
- HYDROCARBON SOLVENT EXTRACTIONS
 - BUTANE • PROPANE
 - PENTANE • HEPTANE



SOLVENT & SOLVENTLESS EXTRACTION METHODS IN COLORADO

APPROVED SOLVENTS FOR MARIJUANA

- SOLVENTLESS EXTRACTIONS
 - DRY SIEVE/SIFT
 - DRY ICE
 - COLD/HOT WATER EXTRACTION
 - HEAT PRESS
- NON-HYDROCARBON SOLVENT EXTRACTIONS
 - ETHYL ALCOHOL/ETHANOL
 - ISOPROPYL ALCOHOL/ISOPROPANOL
 - ACETONE
 - SUPERCRITICAL/SUBCRITICAL CO₂
- HYDROCARBON SOLVENT EXTRACTIONS
 - BUTANE
 - PROPANE
 - PENTANE
 - HEPTANE

APPROVED SOLVENTS FOR INDUSTRIAL HEMP

- HYDROCARBON SOLVENT EXTRACTIONS
 - HEXANE



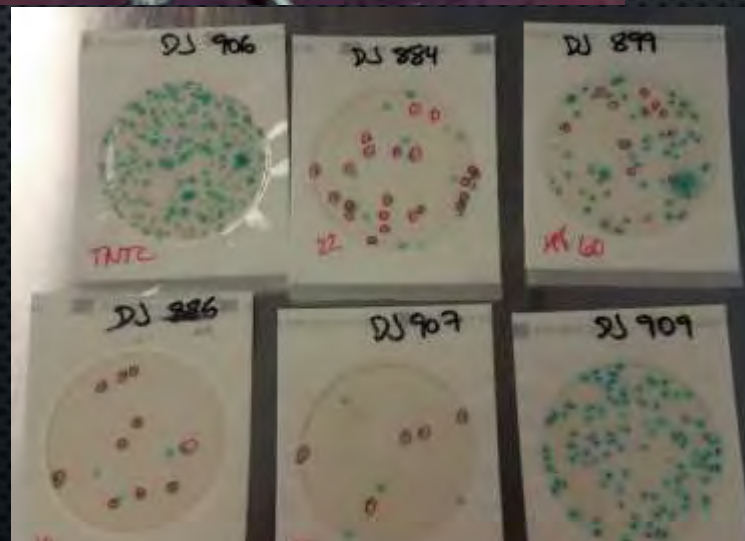
POST-EXTRACTION PROCESSING & REFINEMENT





FOOD SAFETY CHALLENGES

- BASIC FOOD SAFETY KNOWLEDGE & TRAINING (cGMPs, GAPs)
- UNAPPROVED SOURCE
- UNAPPROVED PESTICIDES
- NON-FOOD GRADE INGREDIENTS
- UNWHOLESOME PLANT MATERIAL
- SHELF-STABILITY OF INFUSED EDIBLE OR CONCENTRATE FOR ORAL CONSUMPTION
- REFRIGERATION OF PHFs
- POTENCY AND HOMOGENEITY OF INFUSED PRODUCTS
- UNAPPROVED PESTICIDES & CULTIVATION INGREDIENTS
- RESIDUAL SOLVENTS & ADULTERANTS
- UNAPPROVED AND NON-FOOD GRADE EQUIPMENT
- MISLABELING/MISBRANDING
- TRACEABILITY

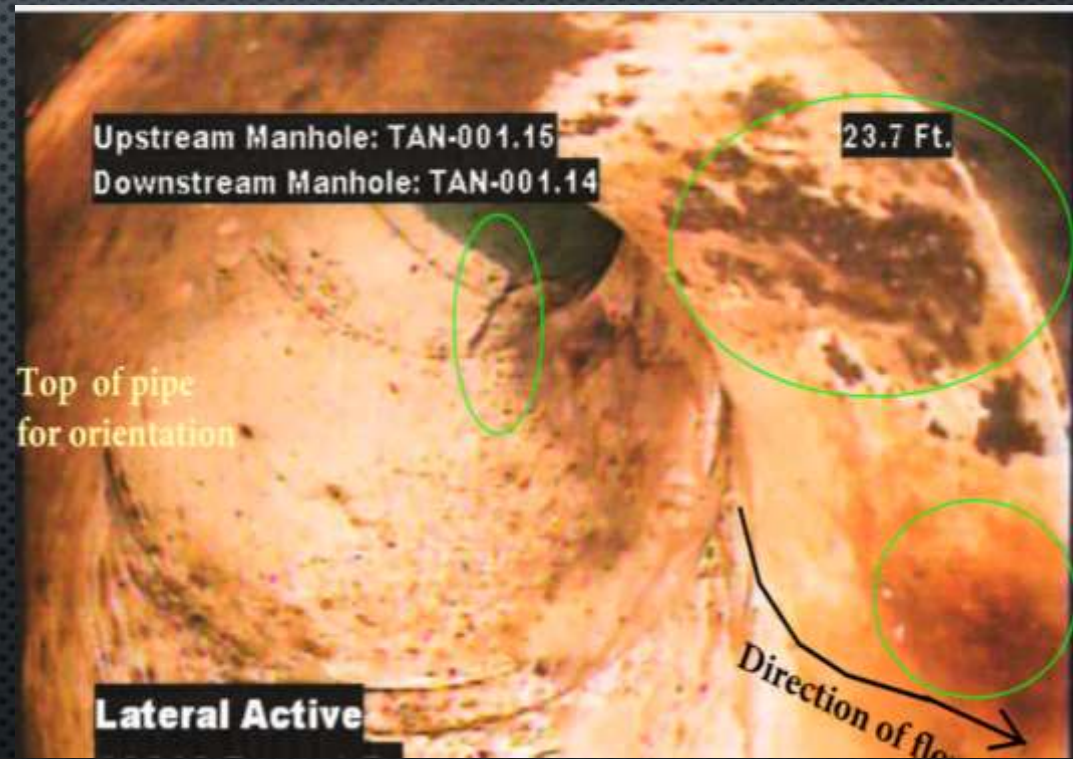


WATER QUALITY CONTROL

STORMWATER DISCHARGES ASSOCIATED WITH “INDUSTRIAL ACTIVITIES” ARE REQUIRED TO OBTAIN **DISCHARGE PERMIT SYSTEM (CDPS) DISCHARGE PERMIT.**

HAZARDOUS MATERIALS & WASTE MANAGEMENT

ANY COMMERCIAL OR INDUSTRIAL OPERATION THAT IS CLASSIFIED AS A HAZARDOUS WASTE GENERATOR (CESQG, SQG, LQG) MUST NOTIFY THE STATE OF REGULATED WASTE ACTIVITY AND APPLY FOR AN **EPA IDENTIFICATION NUMBER** FOR HAZARDOUS WASTE MANIFESTS TO PROPERLY DISPOSE OF HAZARDOUS WASTE.



AIR POLLUTION CONTROL

SOME APPROVED SOLVENTS USED TO EXTRACT AND REFINE CANNABIS CONCENTRATES ARE **VOLATILE ORGANIC COMPOUNDS (VOCs)**.

AN **AIR POLLUTANT EMISSION NOTICE (APEN)** MUST BE FILED FOR AIR POLLUTANT EMISSIONS FROM CONSTRUCTION, MODIFICATION OR ALTERATION OF, ANY FACILITY, PROCESS, OR ACTIVITY WHICH CONSTITUTES **A STATIONARY SOURCE** FROM WHICH AIR POLLUTANTS ARE, OR ARE TO BE, EMITTED.

- CRITERIA POLLUTANTS (VOCs, NO_x, PM, SO₂, & CO)
- NON-CRITERIA POLLUTANTS (HAP)
- LEAD



FIRE & LIFE SAFETY CONCERNS

- FLAMMABILITY OF SOLVENTS
- COLD BURNS/FROST BITE
- HIGH PRESSURE OPERATIONS
- GAS LEAKS
- INSUFFICIENT AIRFLOW
- OXYGEN-DEFICIENT ENVIRONMENT
- FIRE HAZARDS
- INADEQUATE FIRE SUPPRESSION
- NO HAZARDOUS EXHAUST
- ELECTRICAL HAZARDS
- EXTRA SECURITY CONCERNS
- HAZARDOUS CHEMICAL & PESTICIDE EXPOSURES
- WEAPONS, OTHER DRUGS
- BLOCKED MEANS OF EGRESS



CONTACT YOUR STATE AND LOCAL MUNICIPALITY!

- ZONING DEPARTMENT
- BUILDING DEPARTMENT
- FIRE DEPARTMENT
- EXCISE AND LICENSE
- WASTEWATER MANAGEMENT
- ENVIRONMENTAL HEALTH



QUESTIONS?

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