



EXTRACTION, MANUFACTURING & PRODUCT QUALITY OF CANNABIS AND CANNABIS- DERIVED PRODUCTS IN COLORADO

PRESENTED BY THUY VU

DIRECTOR OF OPERATIONS & REGULATORY AFFAIRS

HAMMER ENTERPRISES INTEGRATED SOLUTIONS, LLC

FDA

FDA-2019-N-1482

**SCIENTIFIC DATA AND INFORMATION ABOUT PRODUCTS CONTAINING CANNABIS
OR CANNABIS-DERIVED COMPOUNDS, PUBLIC HEARING**

SILVER SPRING, MARYLAND

MAY 31, 2019

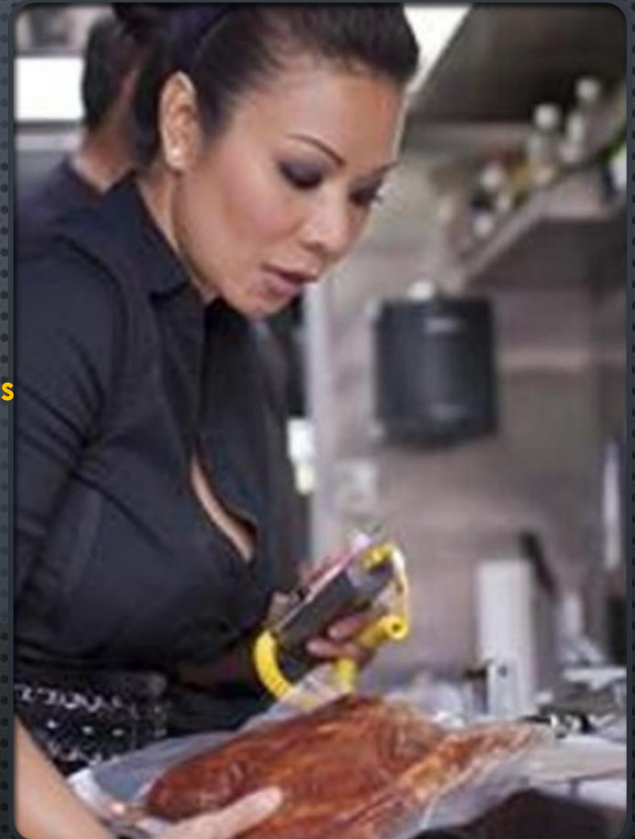
HAMMER ENTERPRISES INTEGRATED SOLUTIONS



- **EST NOVEMBER 2015**
- **ONE OF THE LARGEST VERTICALLY-INTEGRATED INDUSTRIAL HEMP COMPANIES IN COLORADO AND IS THE ONLY CANNABIS COMPANY TO BE AWARDED THE COLORADO DEPARTMENT OF ENVIRONMENT'S ENVIRONMENTAL LEADERSHIP PROGRAM ACHIEVEMENT AWARD.**
- **CUSTOM WHITE LABEL MANUFACTURER OFFERING FULL-SPECTRUM HEMP OIL, CBD ISOLATE, CONCENTRATES, VAPES, TINCTURES, SOFT GELS, TOPICALS, AND GUMMIES.**
- **HAMMER ENTERPRISES IS COMMITTED TO STRICT QUALITY CONTROL GUIDELINES, ETHICAL STANDARDS, AND HIGH INTEGRITY TO DELIVER PESTICIDE-FREE, CHEMICAL-FREE, AND PRESERVATIVE-FREE PRODUCTS.**
- **HAMMER ENTERPRISES IS DEVOTED TO SETTING THE HIGHEST STANDARDS IN THE INDUSTRY, PROMOTING PUBLIC HEALTH, PUBLIC SAFETY, AND ENVIRONMENTAL STEWARDSHIP.**

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



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.



CANYON COURIER

Thursday, June 7, 2018

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Evergreen CBD-based business granted rezoning approval

Plant-oil extraction will be allowed at property on Bryant Drive

By Corinne Westeman
Tuesday, October 24, 2017 at 4:10 pm

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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.”**

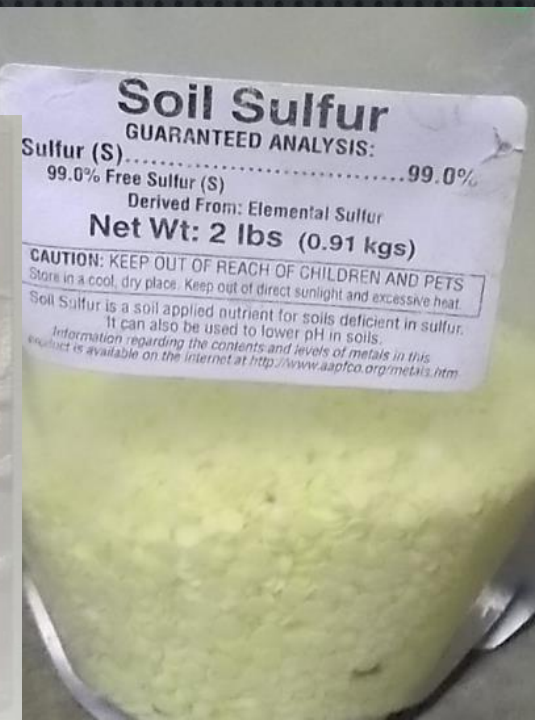
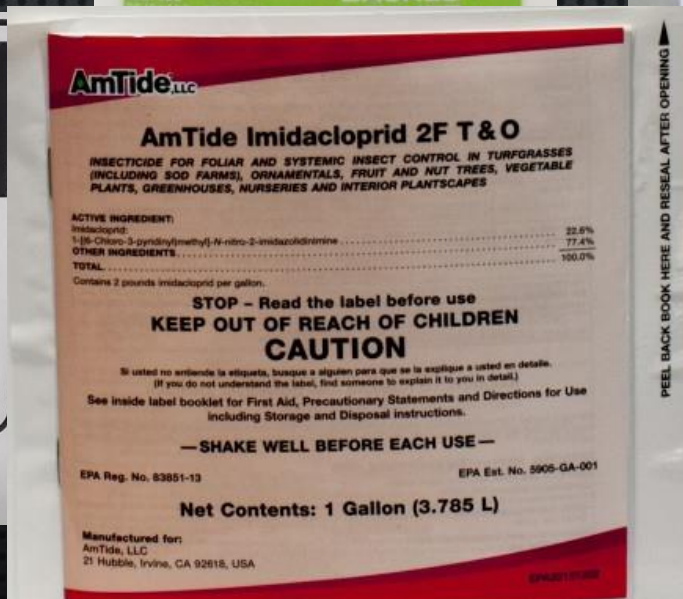


COLORADO DEPARTMENT OF AGRICULTURE



- REGULATES THE REGISTRATION AND CULTIVATION OF **INDUSTRIAL HEMP**.
- COLORADO DEPARTMENT OF AGRICULTURE HAS ADOPTED RULES THAT SET FORTH THE CRITERIA BY WHICH PESTICIDES ARE ALLOWED FOR USE IN THE CULTIVATION OF CANNABIS IN COLORADO 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.**

UNAPPROVED PESTICIDES & CULTIVATION INGREDIENTS





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.



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.
- 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.**

CDPHE'S LABELING REQUIREMENTS

- 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

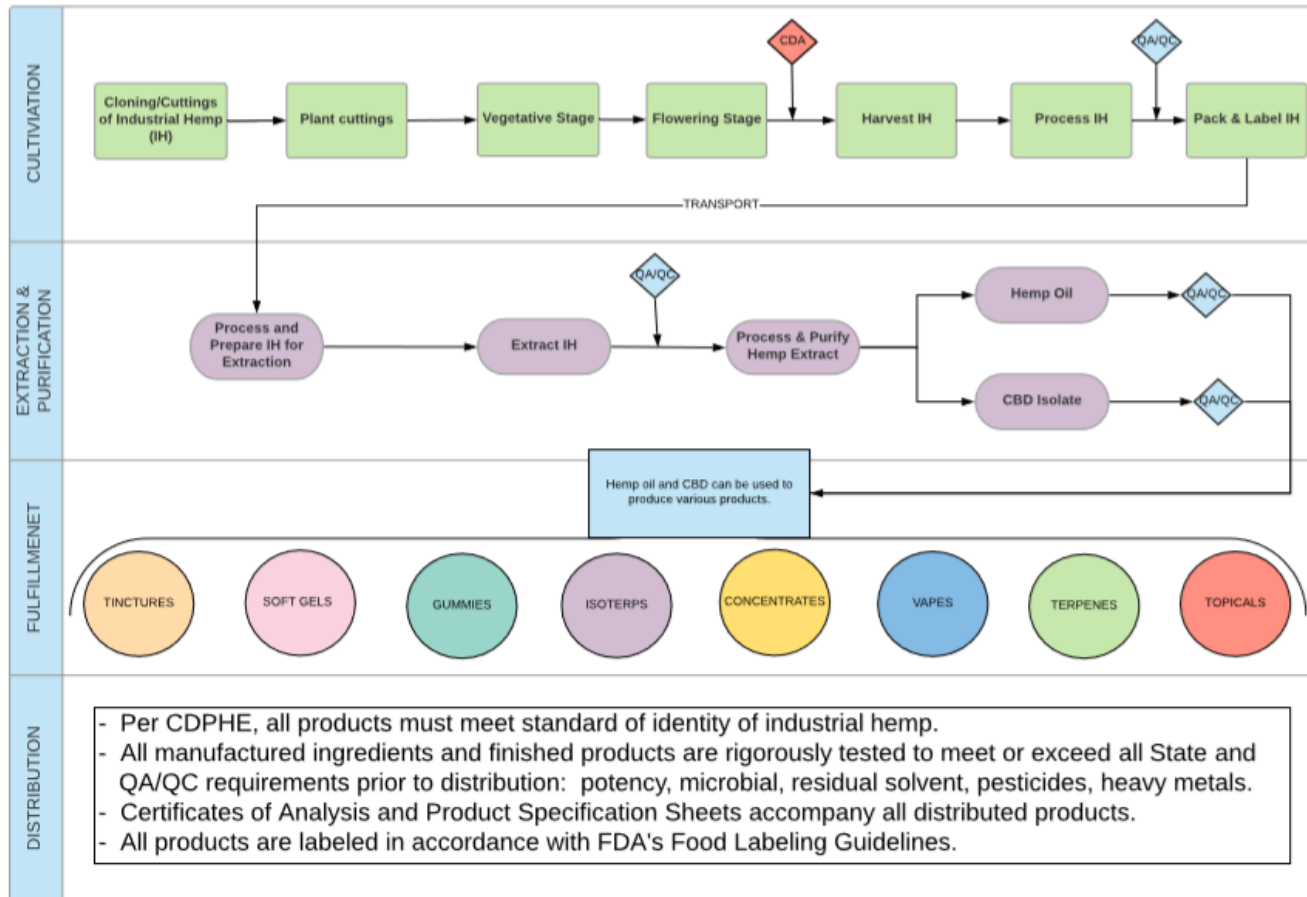
Warehouse and Storage
Facilities

Retailers

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

MANUFACTURING PROCESS

HAMMER ENTERPRISES INTEGRATED SOLUTIONS PROCESS FLOW CHART



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





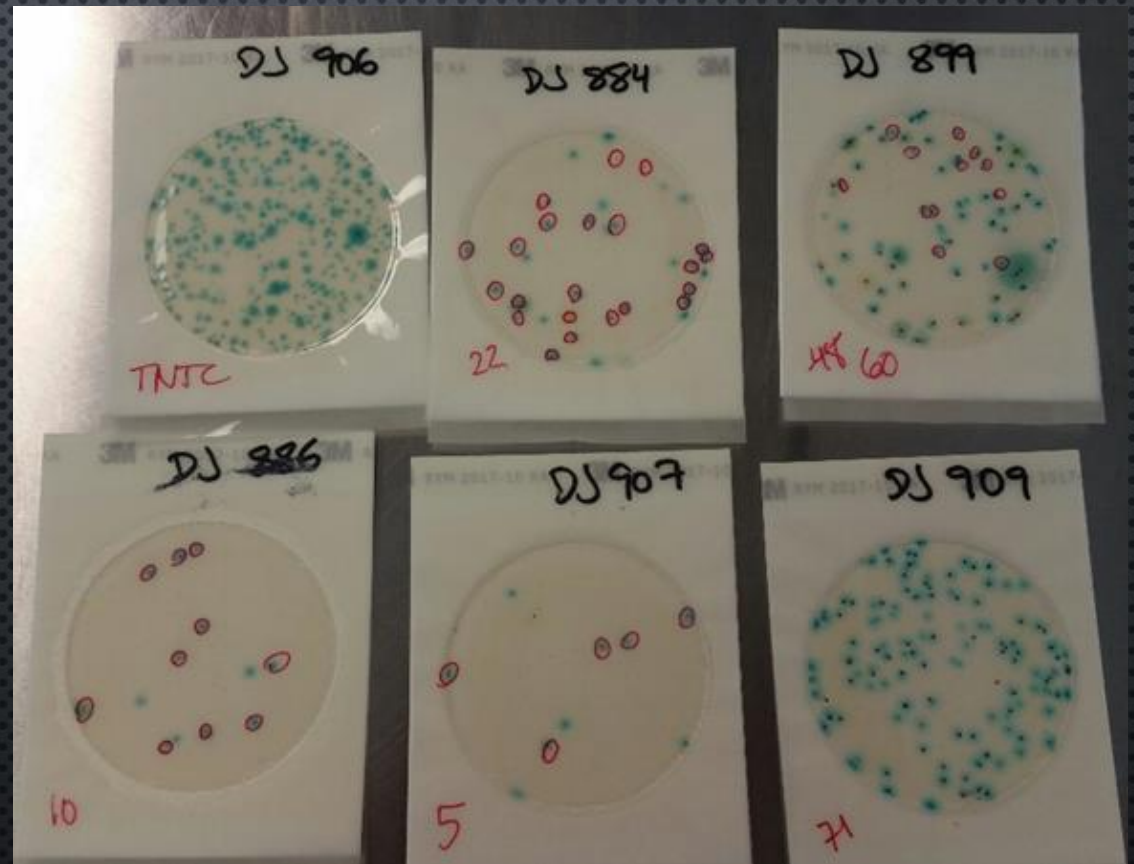
FOOD SAFETY CHALLENGES

- 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



ANALYTICAL TESTING OF RAW, INTERMEDIATE AND FINISHED PRODUCTS

- POTENCY
- RESIDUAL SOLVENT
- MICROBIAL
- MYCOTOXIN
- HEAVY METALS
- PESTICIDES
- MOISTURE ANALYSIS
- WATER ACTIVITY



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