

# FSMA and Mint

GENA REICH  
WSDA FOOD SAFETY PROGRAM

# The Federal Food Safety Modernization Act

- Improving capacity to prevent foodborne illness problems-  
16 sections
- Improving capacity to detect and respond to food safety  
problems - 10 sections
- Improving the safety of Imported foods - 9 sections
- Miscellaneous provisions- 5 sections

# FSMA compliance resulted in new rules:

- Preventative Controls for Human Food: includes modernized Good Manufacturing Practices (GMP's) (subpart B) and several other subparts for entities that have to register with FDA.
- Preventative Controls for Animal Food: same concepts as above for animal feeds
- Produce Safety (peppermint is specifically exempt, spearmint ???)
- Sanitary Transport
- Intentional Adulteration (Contamination)
- Foreign Supplier Verification Program
- Third Party Accreditation

# Preventative Control compliance for mint mix type farms

- Preventative controls for Human Food:
- Subpart A- General provisions
- Subpart B- Modernized Good Manufacturing Practices (GMPs)
- Subpart C- Hazard Analysis and Risk Based Preventative Controls, Mix Type Farm Exempt with attestation but not Processors of mint oil for final users.
- Subpart D- Modified Requirements (attestations)
- Subpart E- Withdrawal of Qualified Facility Exemption
- Subpart F- Requirements applying to records that must be established and maintained
- Subpart G- Supply Chain Program, Mix type Farm Exempt with attestation but not Processors of mint oil for final users

# Implementation Dates

- Large business  $\geq 500$  FTEs: Sept. 19, 2016
- Small business  $< 500$  FTEs: Sept. 18, 2017
- Very small business ( $< \$1$  million average annual sales in 3-year period): Sept. 17, 2018

# Subpart A

## General Provisions

- Definitions
- Exemptions - certain foods, activities and facilities
- Applicability
- Training- qualified individuals

## Subpart A - Definitions

- Food Facility Registration (Bioterrorism Act)
- Facility manufactures, processes, packs, holds human foods
- Subject to Part 117

# Subpart A - Definitions

## Mixed-type facility

- Establishment that engages in both activities exempt from registration and activities that require food facility registration with FDA



## ***Subpart A - Exemptions***

**Farm- Mixed type facility** exempt from subpart C preventive controls & subpart G supply-chain if it is a small or very small business and does :

- low-risk packing or holding activity/food combinations listed in 117.5(g)(3)
- low-risk manufacturing/processing activity and food combinations listed in 117.5(h)(3)
- 117.5(g)(2) describes the foods associated with the activity/food combinations

# *Subpart A - Qualifications of Individuals*

## **117.4: Management ensures individuals are qualified**

- All individuals who manufacture, process, pack or hold food are qualified to perform their assigned duties

# *Subpart A - Qualifications of Individuals*

## **117.4: Qualified Individual - training**

All individuals who manufacture, process, pack or hold food must receive training as appropriate in principles of:

- Food hygiene
  - Employee health
  - Personal hygiene
- Food Safety

# *Subpart A - Qualifications of Individuals*

## **117.4: Qualified Individual - training records**

- Training records for qualified individuals must be established and maintained.

# Subpart F – Requirements Applying to Records

**117.305: Preventive controls records- general requirements**

Qualified Individual training records must meet recordkeeping requirements in subpart F

# Subpart F - Requirements Applying to Records

## 117.315: Record retention:

- All records = 2 years
- Records must be available for official review and copying.

# *Subpart B - Good Manufacturing Practices (GMPs)*

- Applies to all foods, activities and facilities subject to the regulation.
- Similar to “old” GMPs in 21 CFR 110
- Shorter- removed most nonbinding provisions (no “should”)
- Allergen cross-contact

# *Subpart C - Hazard Analysis and Risk-Based Preventive Controls*

- Subpart C applies to most foods, activities and facilities unless an exemption under 117.5 applies.



# Preventative Controls Rule and Registering with FDA

- Farms: raw agricultural (definitions in the rule)-Exempt from registering with FDA
- Mix Type Farms: exempt raw agricultural activities and processing
  - FDA does not see the operation of on farm mint distilleries as “oil harvest”.
  - FDA has decided that mint farm operations with on-farm distilling must register with FDA and are subject to all the Preventative Controls for human food except subparts C and G (with attestation).
  - FDA **agrees** that mint oil is **low risk product**
- Manufacturing/Processing: facilities that process oil to a finished state (for users) are required to register with FDA and will be subject to the entire PC rule.

# WSDA's historical and still current viewpoint

- On farm extraction-Oil harvest, Exempt from WSDA License
- Mint oil processors making ready to use product, WSDA License required. Marketing advantage is access to the WSDA Sanitary Certificates.

## WSDA's look to the future:

- Mint is unique. We want to help you meet the regulations and help coach you try to alter FDA's decision about on farm "harvest" distilling by providing mint industry education for FDA leaders.
- WSDA hopes to continue licensing and inspecting only the mint processors who refine mint oil for sale to the consumer/users and not the farm operations where what we consider to be mint harvesting is done.
- FDA's current position may require us to go inspect on farm mint oil harvesting operations. It is possible we might eventually have to require a WSDA license to help support our costs.

The background is a dark blue gradient. On the right side, there is a complex, glowing structure that resembles a tunnel or a series of overlapping, curved planes. The structure is composed of many thin, parallel lines that create a sense of depth and movement. The lighting is brighter in the center of the structure, creating a strong contrast with the dark background.

Questions?

The background is a dark blue gradient. On the right side, there is a glowing, tunnel-like structure composed of many thin, curved lines that create a sense of depth and movement. The lines are more densely packed and brighter in the center of the tunnel, fading out towards the edges.

Thank you