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Health and Human
Services

Texas Department of State
Health Services

FSMA – A Texas Perspective

Mid-Continental Association of
Food and Drug Officials
February 28, 2018



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Objectives

- Discuss FSMA in Texas
 - GMPS
 - PC
 - Sanitary Transportation
 - Produce Safety
- Discuss the NFSDX Project
- Discuss Challenges and Concerns



A Little History

- February 2013 - Created Workgroup to formulate and submit comments to FDA
- September 2015 – Kicked off state rule-making workgroup
- January 2016 – Began training DSHS staff as FSPCA Lead Instructors
- March 2016 – Attended National Produce Safety Meeting with Texas Department of Agriculture
- August 2016 – Proposed GMP, Preventive Control and Sanitary Transportation rules to DSHS Council for posting in the Texas Register.
- August 2017 - Proposed GMP, Preventive Control and Sanitary Transportation rules final*



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Stakeholder Outreach

- June 2016 and May 2017 Stakeholder Meeting
- August 2016 DSHS Council Public Comment
- December 2016 - Launch of DSHS FSMA Page
- March – May 2017- Official Comment Period
- May 2017-January 2018 – Held 7 FSPCA Alliance PC for Human Food Courses



Comments Received

- Effect on small businesses
 - Cost to document qualified exemption
 - Cost for newly required training
 - Increased cost for small businesses to enter market place
 - Incorporation of federal rules by reference
- Communication with stakeholders
- Need for training and education on industry and inspectors



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Additional Justification

- Impacts of Non-Passage of the Rule Package
- Exemptions to the federal and state rule
- Addressing barriers to small business
- Enforcement
- What is the benefit to the State
- Pulse of the Nation

Adoption Approach

25 Texas Administration Code

§§ 229.210-225

25 TAC §§ 229.210-216 – State language and incorporation of federal requirements found in 21 CFR Part 117 Subpart A.

- §229.210 - Purpose and Scope
- §229.211 - Definitions
- §229.212 - Qualifications of Individuals Who Manufacture, Process, Pack, or Hold Food
- **§229.213 - Exemptions**
- §229.214 - Applicability of 21 Code of Federal Regulations Part 117 Subparts C, D, and G to a Facility Solely Engaged in the Storage of Unexposed Packaged Food
- §229.215 - Applicability of Subchapter N to the Off-farm Packing and Holding of Raw Agricultural Commodities
- §229.216 - Records

Adoption Approach

25 Texas Administration Code

§§ 229.210-225

25 TAC §§ 229.217-224 – Good Manufacturing Practices – Mirror 21 CFR part 117 Subpart B with state specific additions.

- §229.217 Personnel
- §229.218 Plant and Grounds
- §229.219 Sanitary Operations
- §229.220 Sanitary Facilities and Controls
- §229.221 Equipment and Utensils
- §229.222 Production and Process Controls
- §229.223 Natural or Unavoidable Defects in Food for Human Use That Present No Health Hazard
- §229.224 Good Warehousing Practice

Adoption Approach

25 Texas Administration Code

§§ 229.210-225

25 TAC §229.210(d)(19)

d) The department adopts by reference the following laws and regulations

(19) 21 Code of Federal Regulations Part 117 Subpart C, D, F, and G, Current Good Manufacturing Practice, Hazard Analysis, and risk Based Preventive Controls for Human Food, as amended;



Adoption Approach

25 Texas Administration Code

§§ 229.210-225

- Subpart A—General Provisions
- Subpart B--Current Good Manufacturing Practice
- Subpart C--Hazard Analysis and Risk-Based Preventive Controls
- Subpart D--Modified Requirements
- ~~Subpart E--Withdrawal of a Qualified Facility Exemption~~
- Subpart F--Requirements Applying to Records That Must Be Established and Maintained
- Subpart G--Supply-Chain Program

Adoption Approach

25 Texas Administration Code

§§ 229.801-807

Sanitary Transportation of Human Food

- §229.801 Purpose and Scope
- §229.802 Definitions
- §229.803 Vehicles and Transportation Equipment
- §229.804 Transportation Operations
- §229.805 Training
- §229.806 Records
- §229.807 Waivers



Implementation Approach

- Training of all staff in the FSPCA PC for Human Food Course
- Offer FSPCA PC for Human Food Course for Industry at minimal cost
- Time period to discuss observations with management involving new portions of rule
- Time period for no enforcement unless public health concern
- Begin training of staff in PC for Regulators as slots become available



Final Thoughts

- Additional burdens on industry
 - Duplication of efforts
 - Lack of low cost training for industry
- Additional burdens on state programs
 - Duplication of efforts
 - Lack of available training
 - Increased inspection time
- A way to move forward
 - Increased efforts for effective work planning
 - More regional/localized training for both industry and regulatory

National Food Safety Data Exchange (NFSDX)



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SCENARIO	PARTICIPATING STATES
1. State Submits Contracted Inspection Data to FDA	Florida, Illinois*, Iowa*, Minnesota*, Pennsylvania*, and Texas
2. State Requests Firm Data from FDA	Arkansas*, Illinois, Iowa, Minnesota, and Pennsylvania
3. State (Data Requester) Requests Firm Data from Another State (Data Provider)	Arkansas, Illinois, Iowa, and Pennsylvania

*States using USA Food Safety



Who to Contact

- For PFP IT WG membership and POC enrollment please contact:
 - Barbara Thiel, NFSDX Business Program Manager Barbara.Thiel@fda.hhs.gov
- For state participation perspective please contact:
 - Any participant States here at 2018 MCAFDO Conference
 - Matt Colson, Florida Department of Agriculture Environmental Administrator Matthew.Colson@freshfromflorida.com
 - Julie Loera, Texas Food Safety Officer Julie.Loera@dshs.state.tx.us



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Questions?
