

**KAN-DO,  
Program Re-Alignment,  
and  
FSMA**

# Program Re-Alignment

- Stand-up Date: May 15, 2017
- The six regions in the field go away, i.e., no regional office/personnel
- Field labs re-align under Office of Regulatory Science
- KAN-DO becomes a HAF district
  - Human and Animal Food (HAF)

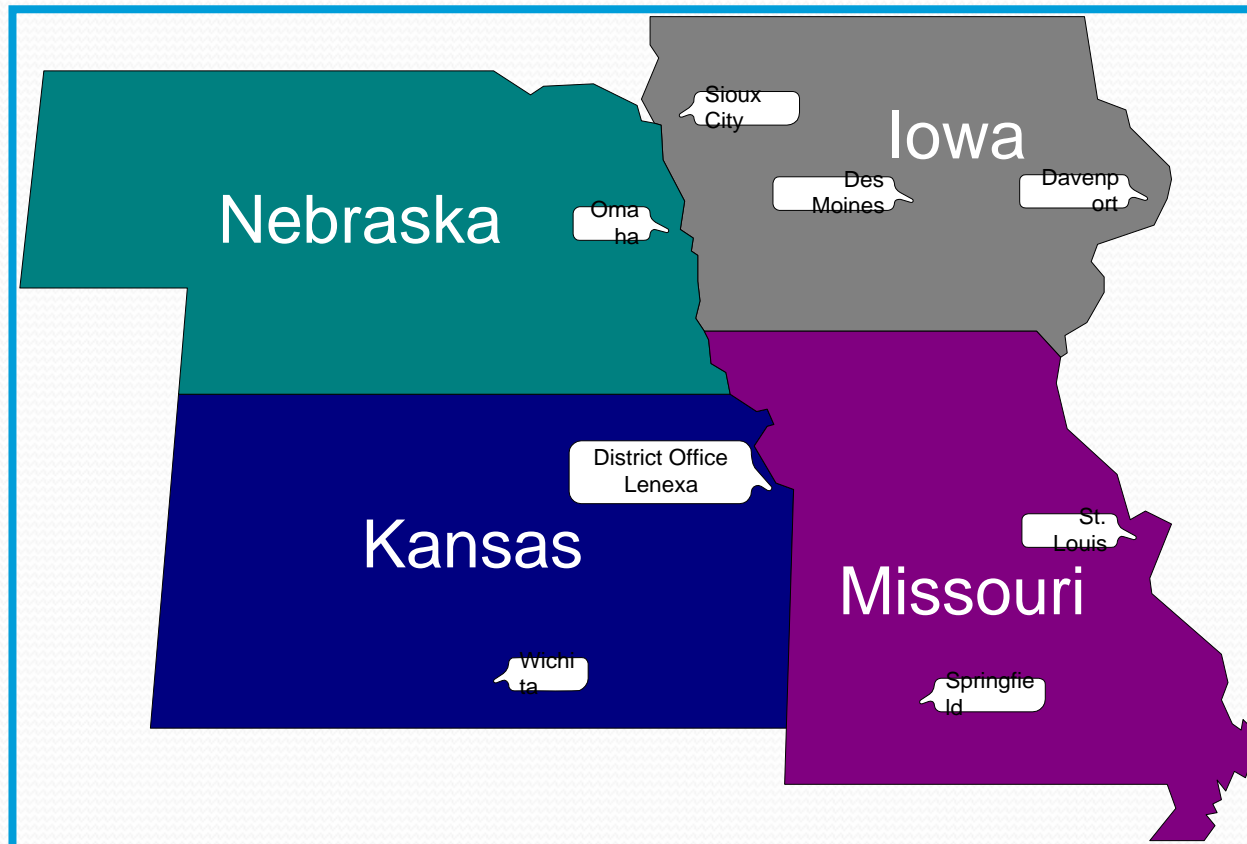
# Program Re-Alignment

## Identity Crisis?

- KAN-DO
- Kansas City District
- HAF 2W (west)
- ?

# Program Alignment

- KAN-DO still covers the four states of Iowa, Missouri, Kansas, and Nebraska





# Program Alignment

- District Management and most of personnel remain together in the HAF program
- Five of the current supervisors remain within the HAF program

# Program Alignment

## Supervisors:

- Melva Palmer – HAF
- Jeff Moody – HAF
- Brittany Terhar – HAF
- Michael Kopf – HAF
- Warren Lopika – HAF
- Brent Hall – Biologics
- Mary Kay Concannon – Medical Devices
- Carl Huffman - Drugs

# Program Re-alignment

- State Contacts remain the same – including State Liaisons and Emergency Response Coordinator
- The processes for state contracts, partnerships, credentialing, etc. remain the same.



# State Contracts, 2016

## Human Food:

- 629, including GMP and acidified food inspections
- 430 environmental samples
- 114 OEI improvements
- 14 phase II audits



# State Contracts, 2016

## Animal Feed:

- 71 licensed mills
- 157 non-licensed mills
- 509 BSE inspections
- 423 samples
- 15 OEI improvements
- 5 tissue residue inspections
- 7 egg inspections

# Food Safety Modernization Act

“I thank the President and members of Congress for recognizing that the burden that foodborne illness places on the American people is too great, and for taking this action.”

*Margaret A. Hamburg, M.D.,  
Commissioner of Food and Drugs*



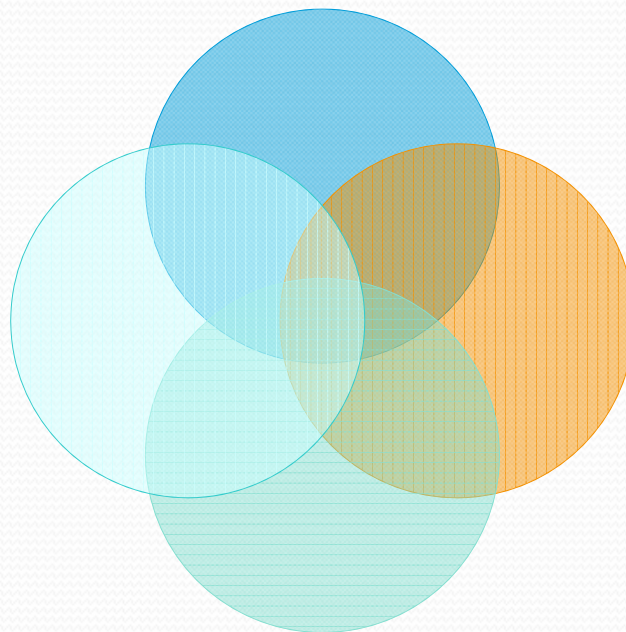
Signed into Law by President Obama on January 4<sup>th</sup>,  
2011



# Main Themes of the Legislation

Prevention

Enhanced  
Partnerships



Inspections,  
Compliance,  
and Response

Import Safety



# Prevention: The cornerstone

Since 2011, FDA has proposed rules for various areas to implement FSMA:

- Comprehensive preventive controls for food and feed facilities
- Safety standards for Produce
- Intentional adulteration standards
- Transportation
- Federal/State Integration
- Prevention in Imports
  - Foreign Supplier Verification
  - Third Party Auditor Accreditation

# Phase 1: Standard Setting



<b>Regulation</b>	<b>Proposal</b>	<b>Final (consent decree)</b>
<b>Preventive Controls (Human Food)*</b>	<b>Jan 16, 2013</b>	<b>Aug 30, 2015</b>
<b>Preventive Controls (Animal Food)*</b>	<b>Oct 29, 2013</b>	<b>Aug 30, 2015</b>
<b>Produce Safety*</b>	<b>Jan 16, 2013</b>	<b>Oct 31, 2015</b>
<b>Foreign Supplier Verification Program*</b>	<b>Jul 29, 2013</b>	<b>Oct 31, 2015</b>
<b>Third Party Accreditation</b>	<b>Jul 29, 2013</b>	<b>Oct 31, 2015</b>
<b>Sanitary Transport</b>	<b>Feb 5, 2014</b>	<b>Mar 31, 2016</b>
<b>Intentional Adulteration</b>	<b>Dec 24, 2013</b>	<b>May 31, 2016</b>

*\*Supplemental proposals published September 2014*

# Compliance Dates by Business Size



Rule	2014	2015		2016	2017	2018	2019	2020	2021
	Dec 15	Aug 30	Oct 31						
Produce Safety	Suppl. Prop.	Final	Final	Large	Large	Water	Water		
	Small			Small	Small	Water	Water		
	V. Small			V. Small	V. Small	Water	Water		
Preventive Controls Human	Suppl. Prop.	Final	Final	Large					
	Small			Small					
	V. Small			V. Small					
Preventive Controls Animal	Suppl. Prop.	Final	Final	Large					
	Small			Small					
	V. Small			V. Small					
FSVP	Suppl. Prop.	Final	Final	Large					
	Small			Small					
	V. Small			V. Small					







# Compliance Dates by Business Size

Rule	2015	2016		2017	2018	2019
	Oct 31	Mar 31	May 31			
Intentional Adulteration			Final	Large		
				Small		
				V. Small		
Sanitary Transport		Final	Large			
			Small			
3 <sup>rd</sup> Party Cert.	Final					

Final Large Small V. Small

# Prevention: Proposed Revisions Announced September 19, 2014

To ensure a more flexible and targeted means for food safety:

- Produce Safety
- Preventive Controls for Human Food
- Preventive Controls for Animal Food
- Foreign Supplier Verification Program

# Prevention Standards Mandates

Sec. 103. Hazard analysis and risk-based preventive controls

Requires human and animal food facilities to:

- Evaluate hazards that could affect food safety;
- Identify and implement preventive controls to prevent hazards;
- Monitor controls and maintain monitoring records; and
- Conduct verification activities.



# Preventive Controls

- Each facility required to have written food safety plan to focus on preventing hazards in foods, including
  - Process controls
    - Biological, Chemical, Physical Safety Hazards
  - Food allergen controls
  - Sanitation controls
  - Supply chain controls
  - Recall plan
- Updated Good Manufacturing Practices

# Preventive Controls

- Training required
  - Preventive Controls for Human Food Course
  - Food Safety Preventive Controls Alliance
    - Management and all HAF designated CSOs have completed this required training
- Final Rule published 2015
- Inspections for preventive controls (and updated GMPs) in human foods initiated in Fall 2016



**New Administration 2017**



# Phase 1: Standard Setting



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# Produce Safety

## Sec. 105. Standards for Produce Safety

- Establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables
- Applies to raw agricultural commodities for which FDA determines that such standards minimize the risk of serious adverse health consequences or death.

# Produce Safety

- Proceeding with rule
- Produce Safety Standards (primarily microbial)
  - Agricultural water
  - Biological soil amendments of animal origin (manure)
  - Worker health and hygiene
  - Equipment, tools, buildings, and sanitation
  - Domesticated and wild animals
- Additional requirements for
  - Sprouts
  - Growing, harvesting, packing, and holding activities
- Produce Safety Network



# Produce Safety Network (PSN)

## Vision

- Support our stakeholders through collaboration and communication
- Provide outreach and technical assistance tailored to the unique conditions of the region
- Educate before and while we regulate

# Produce Safety Network (PSN)

## Produce Safety Network (PSN)

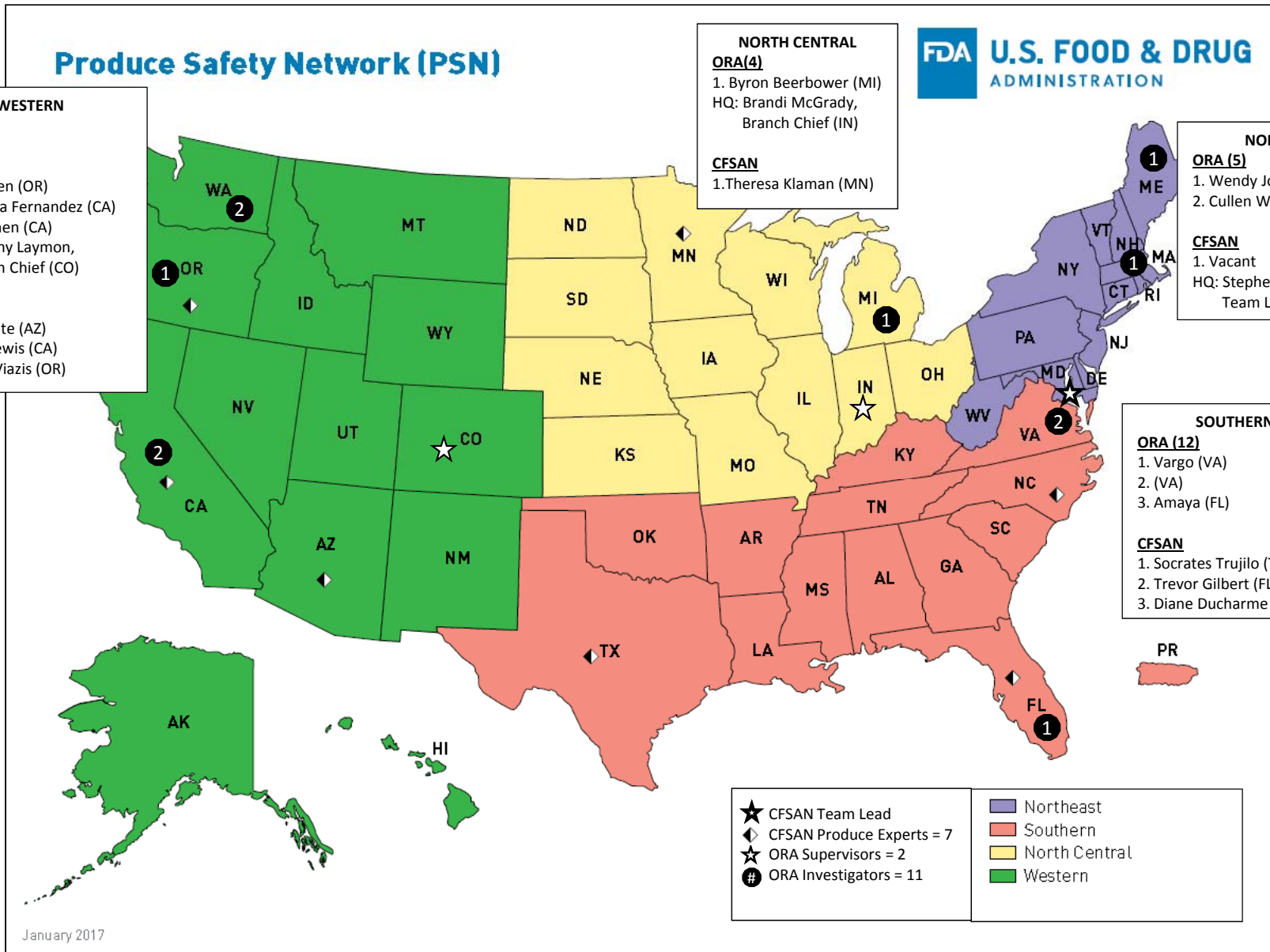


**WESTERN**  
**ORA (15)**  
 1. (WA)  
 2. (WA)  
 3. Kate Allen (OR)  
 4. Estefania Fernandez (CA)  
 5. Mark Chen (CA)  
 HQ: Brittany Laymon, Branch Chief (CO)  
**CFSAN**  
 1. Kurt Nolte (AZ)  
 2. Cindy Lewis (CA)  
 3. Stelios Viazis (OR)

**NORTH CENTRAL**  
**ORA(4)**  
 1. Byron Beerbower (MI)  
 HQ: Brandi McGrady, Branch Chief (IN)  
**CFSAN**  
 1. Theresa Klamann (MN)

**NORTHEAST**  
**ORA (5)**  
 1. Wendy Johncheck (MA)  
 2. Cullen Wilson (ME)  
**CFSAN**  
 1. Vacant  
 HQ: Stephen Hughes, Team Lead (MD)

**SOUTHERN**  
**ORA (12)**  
 1. Vargo (VA)  
 2. (VA)  
 3. Amaya (FL)  
**CFSAN**  
 1. Socrates Trujilo (TX)  
 2. Trevor Gilbert (FL)  
 3. Diane Ducharme (NC)



★ CFSAN Team Lead	■ Northeast
◊ CFSAN Produce Experts = 7	■ Southern
☆ ORA Supervisors = 2	■ North Central
⊙ ORA Investigators = 11	■ Western

# Produce Safety Network (PSN)

## Training and On-Farm Experience for PSN staff

- Interim training process
- DHRD developing produce regulator curriculum
- On-farm experience
  - Key for the PSN to have in-depth knowledge of the region's growing practices and conditions
  - Will be arranged through states and industry associations



# Produce Safety Network (PSN)

## Current PSN Activities

- Program and training development
- On-Farm-Readiness Review (OFRR)

## CFSAN PSN members

- Training
- Engaging with State CAP grantees and other key stakeholders
- Technical assistance

## ORA PSN members

- Onboarding, training and collaboration

# Produce Safety Network (PSN)

## PSN Roles and Responsibilities

- Technical Assistance
- Outreach, Education, and Training
- Work-planning
- Inspections
- Outbreak Investigations

# Produce Safety Network (PSN)

## Closing Points

- The PSN was created to support the implementation of the PSR
- PSN staff will be present at other conferences and training sessions to provide additional information





