

FDA's Preventive Controls Rule:

Common Misconceptions Revealed



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Introduce Speakers



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Agenda

- Food Safety Modernization Act (FSMA) Background
- Preventive Control Rule (PCR) Requirements
- FDA Enforcements
- Implementation Guidelines: Remember “TRED”
- Resources
- Q&A

Food Safety Modernization Act Background



What is the Food Safety Modernization Act?

- **Enactment:** January 4th, 2011
- **Goal:** Major overhaul of the U.S. food safety from a *reactive* to a *preventive* system
- **Seven Pillars of FSMA (yes, it's forced):**
 1. Preventive Control Rule (Human Food)
 2. Preventive Control Rule (Animal Food)
 3. Produce Safety
 4. Foreign Supplier Verification Program (FSVP)
 5. Third-party Accreditation
 6. Sanitary Transportation of Food
 7. Food Defense

Preventive Control Rule Requirements



What is the Preventive Control Rule (PCR)?

- **Battle of the Acronym (HARPC vs PCR):** Hazard Analysis & Risk-based Preventive Controls [Rule]
- **Purpose:** Establish and implement a food safety program for controlling “hazards requiring a preventive control”
- **Who:** A “facility” – required to register as a food facility (manufactures/processes, packs, or holds food)
- **End Result:** Hazard Analysis, Food Safety Plan, Monitoring Records, & Verification/Validation Records

Basic Requirements for the Preventive Control Rule (PCR)

Food Safety Plan

- Hazard analysis
- Preventive controls
- Supplier [verification] program
- Recall plan
- Procedures for monitoring the implementation
- Corrective action procedures
- Verification procedures



POLL

Do you participate in GFSI or a similar food safety scheme?

- Yes, I participate in GFSI or a similar food safety scheme.
- No, I do not.



“I’m ok, I comply with GFSI”

- GFSI (or other schemes) ≠ PCR

	GFSI	PCR
Basis	Private scheme to solve a commercial need	Legal requirement
What if I don't do it?	Lose your contract, less marketable	FDA enforcement (from Warning Letter to Injunction)

- Must conduct a gap analysis

Changing Standard of Compliance

- What if I don't comply with the PCR?

	Before FDA Implemented PCR			
Food Safety Program	No	Yes	No	Yes
Food Adulterants (e.g., pesticide residues)	Yes	Yes	No	No
Compliant?	No	No	Yes	Yes

Changing Standard of Compliance

- What if I don't comply with the PCR?

	After FDA Implemented PCR			
Food Safety Program	No	Yes	No	Yes
Food Adulterants (e.g., pesticide residues)	Yes	Yes	No	No
Compliant?	No	No	No	Yes

cGMPs – Don't Forget

- Updated with the PCR
- Training is now required (among other changes): previously a “should”
- Records: Training on food hygiene and food safety

PCR & FSVP

- **Activity Being Regulated:**
 - **PCR:** Manufacture and storage of food
 - **FSVP:** Importing of food
- **FSVP:** The importer, essentially, verify that foreign supplier is “producing the food in compliance with processes and procedures that provide at least the ***same level of public health protection*** as those required under” the PCR or Produce Safety, and not otherwise adulterated or misbranded due to allergens
- FSVP not required for an importer that is a receiving facility subject to PCR and comply with that regulation

FDA Enforcement



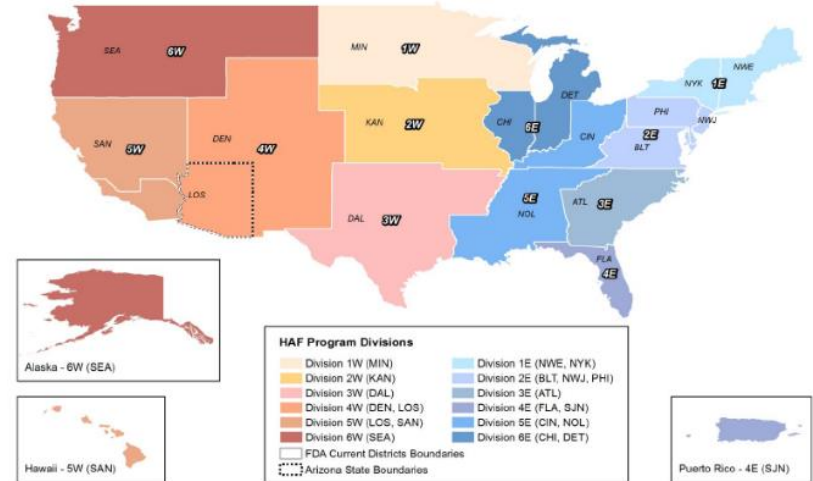
FDA Reorganization (aka “Realignment”)

- **Backstory:** Began in September 2013, and implemented May 2017
- **Program before:** 5 regional offices and 20 district offices (all commodities)
- **Program after:** 7 product/operation offices (commodity specific)

Old



New (foods)



FDA Enforcement of the PCR: How?

- **Staggered Compliance Dates:**

- “Large”: August 30, 2016
- “Small”: August 30, 2017
- “Very Small”: August 30, 2018

- **Approach:**

- Educating while regulating (“We know that this is new territory for food companies; it’s new territory for us too.” ~ Joann Givens, Director of FDA’s Office of Human and Animal Food Operations – West)
- Taking a risk-based approach
- Providing “Real-time” feedback
 - “Strengthened, real-time subject matter expert support for frontline oversight activities before, during and after inspections”
 - “Streamlined processes to enable real-time decisions regarding frontline corrective actions, enforcement, and other measures to achieve public health and consumer protection”
 - “Well-defined processes for timely resolution, at the appropriate level, of broader strategy and policy issues”

From FDA, Operational Strategy for Implementing the FDA Food Safety Modernization Act



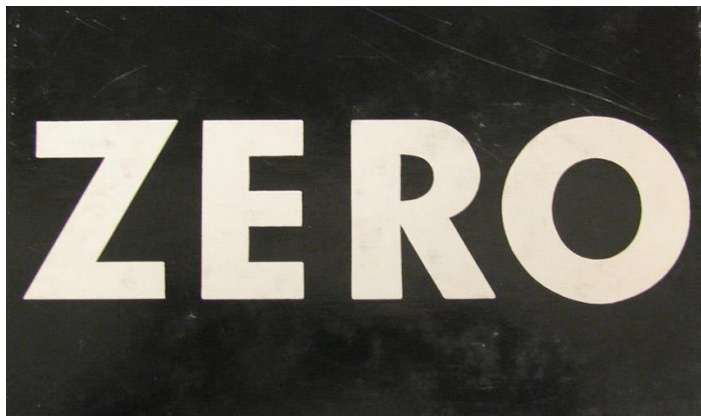
POLL

How many enforcement actions have taken place from the FDA?

- 0 – 10
- 11 – 50
- 51 – 100
- Over 100



FDA Enforcement of the PCR: What We've Seen



Public Enforcements

- No “public” enforcement of PCR (no Warning Letters or citation in other enforcement actions)
- **Not surprising:**
 - Publically stated focus is on “create a culture of food safety, a culture of compliance with procedures, processes, and practices” (~Joann Givens)
 - First Warning Letter for Dietary Supplement cGMPs , two years after the first compliance date

How to Primer

- Read & understand the regulations
- Perform gap assessment
- Look at what you have versus what you lack
- Plan and execute
- Ensure ALL hands on deck
- Review progress regularly
- Journey without a destination





POLL

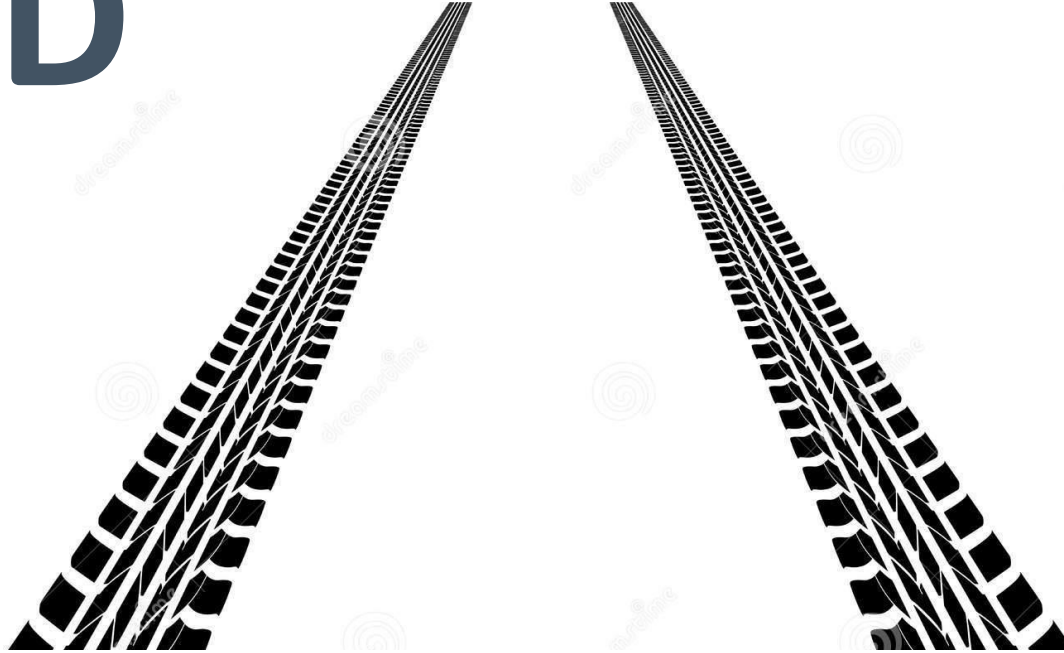
Do the documents your plant generates for your food safety program today tell the complete history of the product(s) produced?

- Always
- Most of the time
- Sometimes
- Not sure



Implementation Guideline: Remember “TRED”

TRED



T's

- Test your systems — practice makes perfect
 - Thorough
 - Tough
- Think outside the box
- Transparency is a must
- Train, engage and utilize your front line workers — they are the key to success

R's

- Regulations are law
- Recognize the new reality – just do It!
- Remake your culture
- Regular reinforcement and accountability
- Read
- Review
- Reanalysis

E's

- Empowerment
- Engagement
- Encouragement
- Excitement
- Exponential effort

D's

- “Do what you say and say what you do”
- Document what you did — records are critical
- Devil’s in the details
- Do utilize signatures/initials as required and for accountability
- Dates and time matter

You Can't Afford Not To!

- Meet the new requirements head on!
- Expanded programs are value added — not a necessary evil!
- Recall risks
 - Loss of reputation
 - Loss of business
 - Costly
 - Time intensive
 - Rolling
 - Bring media attention

ROI

There is a return on investment

- Robust fully implemented processes run more efficiently
- Trained employees know what to do, how to do it, are more engaged
- Robust documentation tells the whole story
- Proactive is easier than reactive

Resources



FSMA Preventive Controls for Human Food Courses



All-New!

Blended eLearning Course

In-Person Classroom Course

To learn more about our **FSMA Preventive Controls for Human Food Courses** visit:
<http://www.alchemysystems.com/food-production/events/preventive-control/>

Alchemy's Training, Coaching & Reinforcement Programs

Educate your workforce to speed your way to FSMA compliance.

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- Ensure accurate recordkeeping with automated documentation and audit-ready reporting



The background is a night-time photograph of the Austin skyline, featuring the illuminated towers of the Marriott Marquis and the Frost Tower. In the foreground, there is a river with a bridge and some greenery. Overlaid on the left side of the image is a network diagram consisting of blue and green dots connected by lines. The text 'alchemy' is in a white, lowercase, sans-serif font, and 'engage' is in a larger, white, lowercase, serif font, both centered horizontally and partially overlapping the skyline and the network diagram.

alchemy engage

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Q & A



THANK YOU

