FSMA Update

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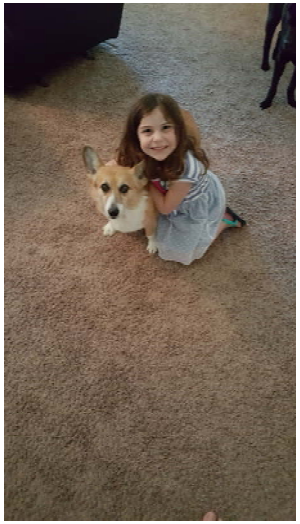
Background Information

A Little About Me

- Received my Bachelors from the University of Florida.
- Received my Masters from the University of Arkansas.
- Working at Tyson for 6 years, currently Associate Director of Food Safety and Regulatory Compliance.
- Oversee the regulatory compliance for all Tyson FDA registered establishments, as well as, oversee all GFSI efforts and FSQA policies.



Tyson Foods

- Currently have 105 FDA registered facilities.
- 10 bakery facilities, including 4 tortilla plants.
- Other facility categories include:
  - Entrée meals;
  - Meal Kits;
  - Seafood;
  - Finished Pet Treats;
  - Animal Food Ingredients;
  - Animal Feed Ingredients; and
  - Distribution Centers.

FSMA is Huge!

- I may not cover all FSMA topics today.
- We are going to be fitting a lot of information in a short period.
- Feel free to ask questions during or after the presentation.

Summary

1

FSMA Overview and FDA Landscape.

2

What have we learned and where should we be focusing our attention?

3

What tools are available to assist plant management in preparing for FSMA?

FSMA Overview

What is FSMA?

- The Food Safety Modernization Act was written into law by President Obama in January 2011.
- Broken out into 7 final rules.
- Is stated as being the most sweeping reform of food safety law since the Food, Drug, and Cosmetic Act of 1938.

Why is FSMA Important?

- All FDA regulated facilities, with few exceptions, must register with the FDA and comply with the law.
- Currently, the FDA regulated industry is more reactive to food safety issues.
- FDA wants the food industry to become more proactive by using a science and risk-based approach (HACCP-Like) to food safety.

What are the 7 Final Rules?

1. Produce Safety;
2. Preventive Controls for Human Food;
3. Preventive Controls for Animal Food;
4. Strategies to Protect Food Against Intentional Adulteration;
5. Foreign Supplier Verification Programs (FSVP) for Importers of Food for Human and Animals;
6. Accredited Third-Party Certification; and
7. Sanitary Transportation of Human and Animal Food.

Compliance Dates

	PC for Humans	Sanitary Transport	Foreign Supplier Verification	Intentional Adulteration
Large Company	September 19, 2016	April 6, 2017	May 17, 2017	May 28, 2019
*Small Company	September 18, 2017	April 6, 2018	May 17, 2017	May 28, 2020
**Very Small Company	September 17, 2018	N/A	May 17, 2017	May 28, 2021

**Small Company – A company that has <500 total employees (this includes the entire corporation and not just one facility).*

*** Very Small Company – A company that has annual food sales below the applicable limit defined for each rule (see the specific rule for exact numbers).*

PC Rule

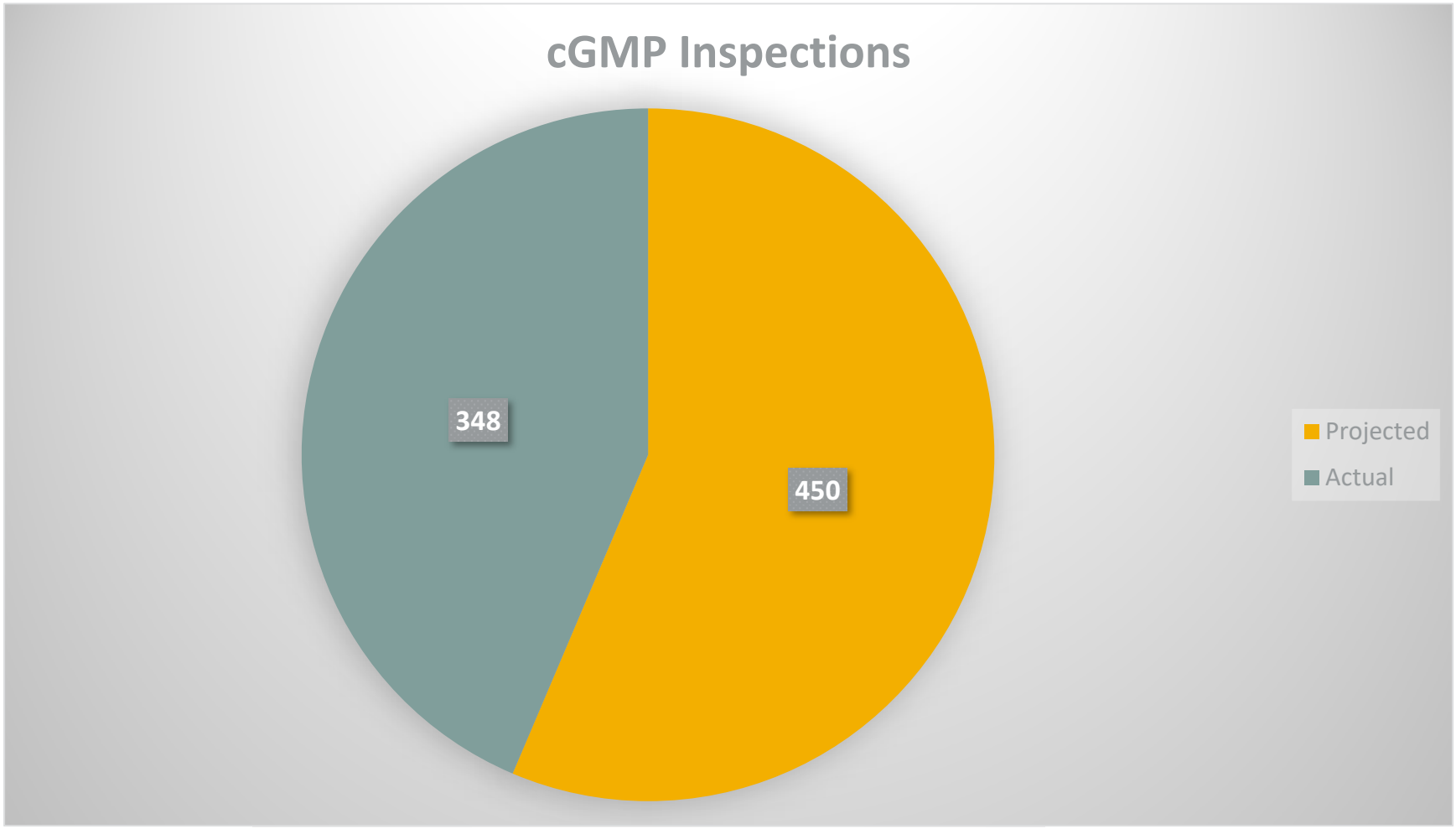
Our main focus for this presentation will be the PC for human food.

FDA Landscape

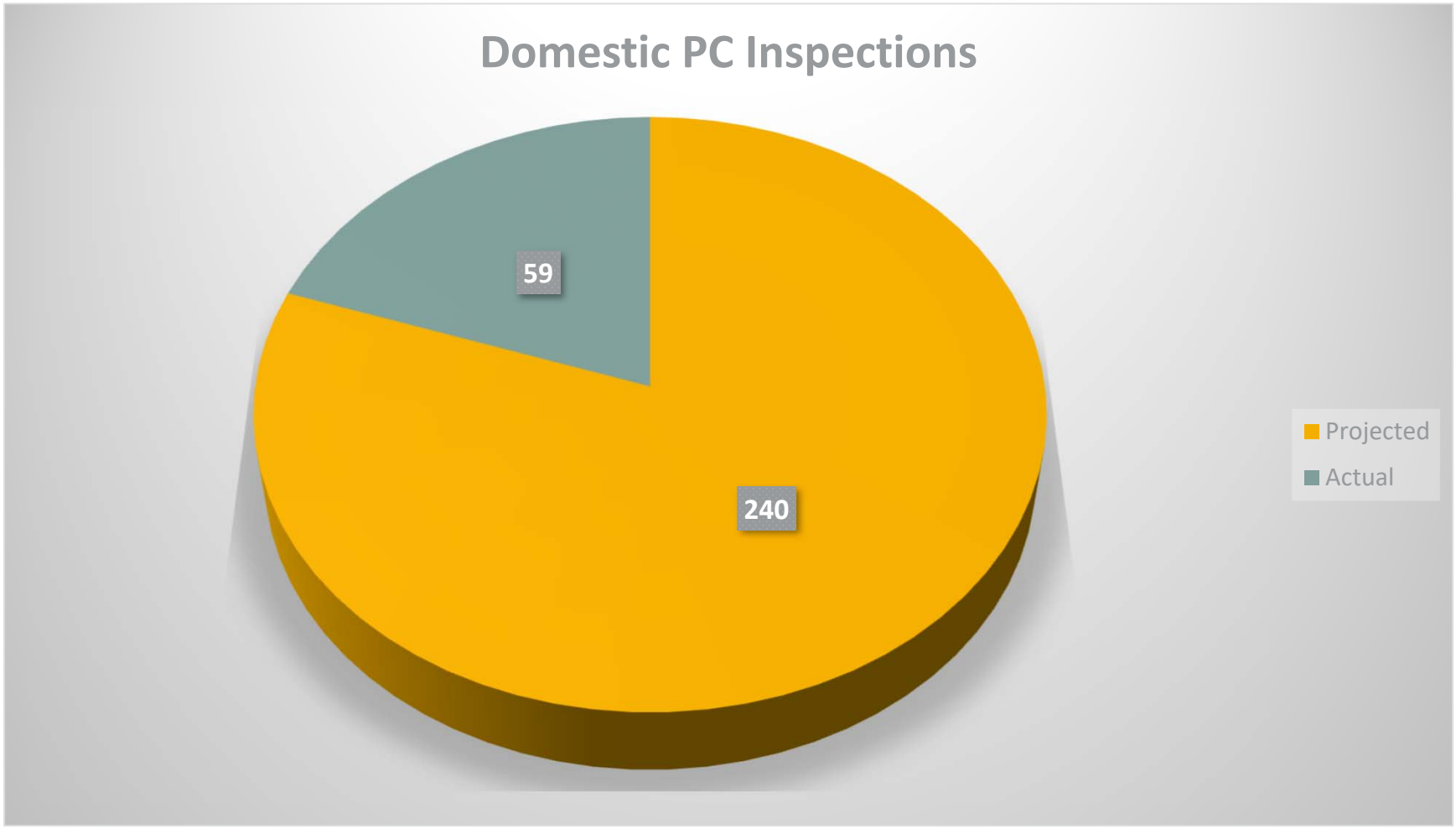
Inspections

- FDA stated that for FY2017 that they anticipated 300 preventive control inspections.
  - 240 domestic, 60 foreign.
  - 30 trained inspectors conducting 10 inspections each.
- FDA inspectors would take FSPCA PCQI training prior to conducting inspections just like the rest of the industry.

FY 2017 Current Good Manufacturing Inspections



FY 2017 Preventive Controls Inspections



Inspections

- We know FDA does not have the resources to conduct necessary inspections.
- Agency is relying heavily on the state departments to conduct FDA inspections.
- There have been 3 different types of inspections conducted:
  1. PC Inspections
  2. Modern GMP Inspections
  3. GMP inspections

Inspection Duration

- Inspection duration depends on type of inspection.
- State agencies have historically lasted 0.5-1day.
- Federal inspections have lasted longer, especially PC inspections.
- You won't know until the inspector shows up!

Preventive Controls Rule Overview

Subparts

- A – General Provisions
- **B – cGMPs**
- **C – Hazard Analysis and Risk-Based Preventive Controls**
- D – Modified Requirements
- E – Withdrawal of a Qualified Facility
- F – Records
- **G – Supply Chain Program**

Terminology

- Qualified Individual
  - Think hourly
  - Has to have GMP training and a basic understanding of food safety.
- Preventive Controls Qualified Individual
  - Think Management
  - Has to have GMP training, a basic understanding of food safety, and has to have experience or training that makes them qualified to implement the food safety plan.
- Beware that definitions and implementation are not always equal!

Minimum Expectations

- Train or hire a PCQI.
- Follow GMPs (21 CFR 117 Subpart B).
- Understand your process and where your products are sold.
- Develop a flow chart.
- Create a food safety plan.
- Identify critical processing steps.
- Validate your decisions.

Major Focus Areas for Bakery Industry

Operations Team from Springfield, State

The Food Safety Plan

- Understand your process and where your products are sold.
- Create a thorough hazard analysis.
- Identify the critical processing steps that affect food safety, **not quality**.
- Set up monitoring, verification, records, and corrective actions for all PCs.
- Validate everything.

Allergen Control

- Allergens are the #1 cause of recalls.
- If allergens are present, you must address allergens in your food safety plan.
- How do you prevent allergen cross contamination in your facility (e.g. dust collectors, employee practices, separation of processes, etc.)?

Allergen Control

- All allergens must be labelled on the finished product if Big 8 allergens are present (FALCPA)
- Label Verification
  - Incoming ingredients should be verified for allergens.
  - Finished products should be verified for accuracy **before** shipping products.

Sanitation Controls

- How often are you cleaning your facility?
- Wet clean vs. dry clean
- This can be addressed through GMPs, SSOPs, or through environmental monitoring program.
- How do you validate your process to prove to the FDA that you are running a clean operation?

Extended Runs

- These are operations that run more than 24 hours without a full sanitation clean up.
- How long can you run before you have to break down equipment and clean?
- Do you have the data to support that decision?
  - This should be based on micro requirements and not customer orders.

Environmental Monitoring

- If you produce an RTE product, then you should have an environmental monitoring program.
- Don’t be fooled by the water activity of tortillas, microorganisms can still grow.
- FDA is putting a lot of focus on bakeries and their environments.

Environmental Monitoring

- FDA just updated their *Listeria* compliance guidelines.
- It is now acceptable to test contact and non-contact sites.
- Beware of FDA swabathons
  - 100 to 300 swabs of your facility.
  - No sites are off limits!

Sentinel Site Program ®

- Tyson Foods copyrighted environmental monitoring program.
- FDA approved.
- You can request a copy of the program and utilize in your facility.

Suppliers

- Suppliers must be addressed in the food safety plan when hazards are identified.
- Understand the ingredients coming into your facility.
- Do your suppliers know to contact you when there is a change to their ingredient?
- Who is controlling your identified hazards?

Good Manufacturing Practices

- Seems so simple, yet we often miss the boat.
- How do you train your employees?
- Do you employees understand food safety and the "why" behind what you do?
- "This is what we've done for the last 50 years," is no longer going to fly.
- Don't be on the Wednesday warning letters!

Tools

FSPCA Preventive Controls for Human Food

- FSPCA website - https://www.ifsh.iit.edu/fspca.
- This course is FDA endorsed.
- Provides FSMA training and participants will become PCQIs after completion.
- Beware of consultants offering training that have no bakery background.
  - Suggest using a local trainer or trade organization for cost effectiveness.

Food Safety Plan Builder

- A great tool for novice HACCP employees.
- A step by step approach to building an effective food safety plan.
- https://www.fda.gov/food/guidanceregulation/fsma/ucm539791.htm

Compliance Guidelines

- These are not set in stone, but give the FDA's current thinking on topics.
- Current guidance documents include:
  - Control of *Listeria monocytogenes;*
  - Hazard analysis and risk-based preventive controls; and
  - Hazards that need preventive controls.
- https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm

Other FSMA Tools

- The Food Defense Plan Builder
  - Step by step approach to facility defense
  - https://www.fda.gov/food/fooddefense/toolseducationalmaterials/ucm349888.htm
- Carrier training for the sanitary transportation rule
  - https://www.fda.gov/food/guidanceregulation/fsma/ucm576097.htm

Raise the world's expectations
for how much good
food can do.

Questions?