

How FSMA Impacts Pest Control in the Food Industry



Objectives

- Explore the impact of the Preventive Controls Rule for Human Food on pest management in food manufacturing and distribution.
- Discuss ways to successfully meet these challenges.



Content

- What the FDA says
- What has changed and what has not
- The “teeth” of FDA’s food safety law
- The word “may” explained
- Preventive Controls Rule challenges for pest management



FDA says...

“The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.”



What Changed...and What Has Not

From Reaction to Prevention

From 402(a)(3) to 402(a)(4)

(3) A food **shall** be deemed to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or it is otherwise unfit for food.

(4) A food **shall** be deemed adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated or whereby it **may** have been rendered injurious to health.



What Changed...and What Has Not

Inspection, Compliance, and Response

–From “credible and verifiable information” to “reason to believe”

- The SAHCOHHA threshold
 - Records are subject to review
 - Similar products will be suspect



The "Teeth" of FDA's Food Safety Law

- Prevention is not new, but Congress has given the FDA authority to use the criteria more broadly and assertive
 - Documentation review
 - Product detention
 - Recalls
 - Import prohibition
 - Injunctions
 - Litigation / criminal prosecution



"May" Explained...

§ 117.37 Sanitary facilities and controls

- ***Pest control.*** *Pests must not be allowed in any area of a food plant. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of food on the premises by pests.*

So, what are effective measures?



Where are We?

Findings per Category			
	IN	S	U
Category	%	%	%
Adequacy of Prerequisite and Food Safety Programs	27.14	43.63	11.8
Cleaning Practices	13.74	10.37	21.88
Integrated Pest Management	10.74	7.78	19.60
Maintenance for Food Safety	32.30	26.03	36.08
Operational Methods and Personnel Practices	16.04	12.20	11.36

IN = Improvement Needed
 S = Serious
 U = Unsatisfactory

Out of total Findings August 1, 2015-July 31, 2016



Where are We?

Top Five Unsatisfactory Findings	
Category/Standard	U %
Maintenance for Food Safety Ceiling and overhead structures	18.75
Equipment and utensil construction	11.65
Cleaning Practices Product zone cleaning	17.61
Integrated Pest Management	
Pest habitat	7.39
Pesticide control	5.68

U = Unsatisfactory

Out of total Findings August 1, 2015-July 31, 2016



Where are We?

Top IPM Findings			
Standard	IN %	S %	U %
Pest habitat	12.28	43.06	34.78
Interior rodent monitoring devices	11.92	-	7.25
Pesticide application documentation	-	13.89	-
Pesticide control	-	5.56	26.09
Facility assessment	7.65	-	-
Bird Control	5.69	5.56	8.70
Signed contracts	6.76	-	-
IPM program	-	5.56	-

IN = Improvement Needed

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Out of total Findings August 1, 2015-July 31, 2016



“May” Explained...

- **Effective measures** to:
 - Exclude
 - Prevent
 - Protect

Let's take a look



Effective Measures to Exclude / Prevent Pests

Grounds

Meets sanitary requirements?



Effective Measures to Exclude / Prevent Pests

Grounds

A little overgrown?



Effective Measures to Exclude / Prevent Pests

Grounds

Only during the rainy season



Only water and decaying organic matter?



Effective Measures to Exclude / Prevent Pests

Grounds

We might need it some day!



Effective Measures to Exclude / Prevent Pests

Plant

Effective exclusion measures?



Effective Measures to Exclude / Prevent Pests

Plant



Is there a screen?



Why is it open?



Effective Measures to Exclude / Prevent Pests

Plant



Why is it open?

Why is it shut?



Effective Measures to Exclude / Prevent Pests

Plant and Grounds



Well-designed, maintained, monitored?



Effective Measures to Exclude / Prevent Pests

Receiving

Sanitary operations?



Effective Measures to Exclude / Prevent Pests

Warehouse

It is locked, isn't it?



Effective Measures to Exclude / Prevent Pests

Warehouse

Just a spill?



Effective Measures to Exclude / Prevent Pests

Production

Why covers?



Effective Measures to Exclude / Prevent Pests

Production

It is just a temporary repair with corrugated carton.



Effective Measures to Exclude / Prevent Pests

Floors

What happened to maintenance?



Effective Measures to Exclude / Prevent Pests

Floors

I left my trails, what else do you want?



Effective Measures to Exclude / Prevent Pests

Floors

Well-designed and maintained?



Effective Measures to Exclude / Prevent Pests

Ceilings and Overheads

We can see the sky!



Effective Measures to Exclude / Prevent Pests

Ceilings and Overheads

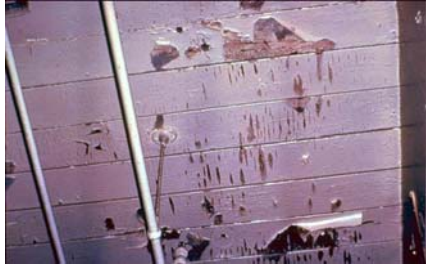
We contained the roof leak!



Effective Measures to Exclude / Prevent Pests

Ceilings and Overheads

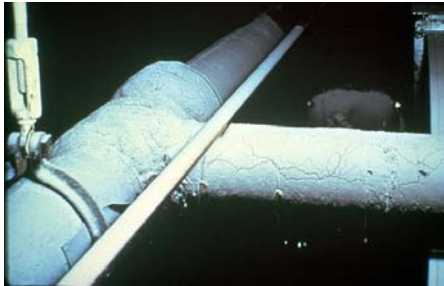
What does missing paint have to do with pests?



Effective Measures to Exclude / Prevent Pests

Product Zone Cleaning

Very difficult to get to!



Effective Measures to Exclude / Prevent Pests

Product Zone Cleaning

Just a little mold?



Effective Measures to Exclude / Prevent Pests

Receiving and Shipping

Do pests take rides?



Effective Measures to Exclude / Prevent Pests

Employees and Employee Areas

Any connection to pest issue?



Effective Measures to Exclude / Prevent Pests

Chemical Control

Is it under control?



Question

Is there anything else important for pest management under the Preventive Controls Rule?

Let's explore!



The Challenge of Subpart C: HARPC

Requires:

- Identification of “**known or reasonable foreseeable hazards**” associated with
 - Product (raw materials, ingredients, rework, and finished product)
 - Process
 - Manufacturing environment



The Challenge of Subpart C: HARPC

Requires:

- Documentation of such hazards
- Utilization of *science* and *risk analysis* to:
 - Define *appropriate* preventive controls (PCs)
 - Identify who will apply the PCs and be held accountable
 - Manage the PCs in an *adequate* manner
- *Records*: document application of management elements



The Challenge of Subpart C: HARPC

Question -

What does this summary of Subpart C of the PC Rule mean for pest management?



The Challenge of Subpart C: HARPC

- What science is relevant?
- How is the scientific knowledge applied in different types of facilities?



The Challenge of Subpart C: HARPC

How is an effective pest risk assessment undertaken in a food manufacturing and distribution environment?



The Challenge of Subpart C: HARPC

- What are the *basic preventive measures* and how are these applied in an effective manner?
- How to deploy and manage an initial comprehensive pest monitoring system?



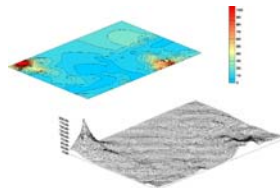
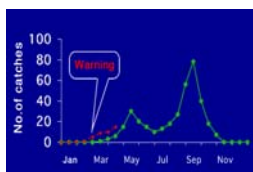
The Challenge of Subpart C: HARPC

- How to set up and defend specific inspection frequencies?
- Why and how to adjust the inspection frequencies?
- Why, how, and when to change the basic monitoring system?



The Challenge of Subpart C: HARPC

How to do predictive analysis and differentiate between acceptable and nonacceptable?



The Challenge of Subpart C: HARPC

- How to deal with repeat issues?
- How to defend “programmed” pesticide applications?



The Challenge of Subpart C: HARPC

- Are the records audit proof?
- Who, how, and when will records be provided to the FDA, if requested?



The Challenge of Subpart C: HARPC

- How is the value of prevention demonstrated?
- How is facility management convinced that prevention is an *investment* with a return and not an annual cost to be minimize?



Key Takeaways

- Sanitary conditions is the key criteria by which plants will be judged = 402(a)(4)
- The use of science and risk assessment is essential for an effective Pest Management Program (PMP).
- The PMP is not a static tool.
- Records must demonstrate the true conditions under which the product was manufactured and are subject to review by the FDA.
- Convincing management that prevention pays is absolutely essential.



Questions