

HACCP v. HARPC

Critical Control Points and Risk Based
Preventive Controls



Where we are going today:

- Brief introduction to HACCP
- Brief introduction to HARPC
- Discuss at least five differences between the two paradigms
- Discuss that there are other differences that we will not be talking about today



What is HACCP?

- How to make food safe without testing.
- Recognition that science can make food safe
- Here is how we do it:
 1. Hazard Analysis
 2. Critical Control Point identification
 3. Establishment of Critical Limits
 4. Monitoring Procedures
 5. Corrective Actions
 6. Record Keeping
 7. Verification Procedures

Here is a visual:

Potentially
contaminated
food

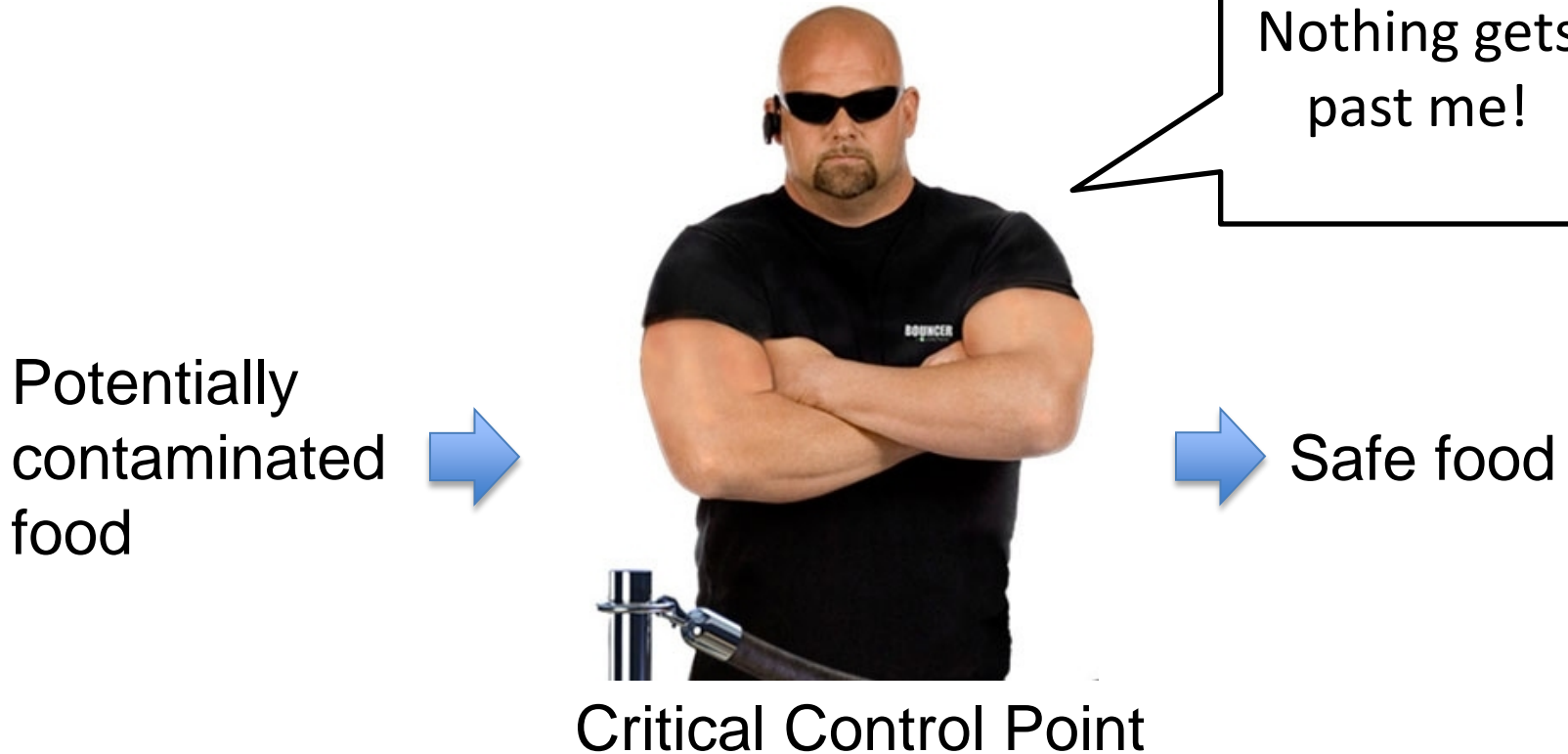


Safe food

Nothing gets
past me!

Critical Control Point

Here is a visual:



Why do we still have food safety issues?

What is HARPC then?

- Focus on the process of keeping food safe
- Recognition that overall execution makes food safe
- Here is how we do it:
 1. Written Analysis of Hazards
 2. Identification of Preventive Controls
 3. Monitoring of Preventive Controls
 4. Corrective Actions for Ineffective or absent Preventive Controls
 5. Verification of Preventive Controls
 6. Preventive Control Records

Here is a visual:

Lets
continually
evaluate!

Potentially
contaminated
food



Safe food

Preventive controls

Side by side analysis

HARPC

1. Written Analysis of Hazards
2. Identification of Preventive Controls
3. Monitoring of Preventive Controls
4. Corrective Actions for Ineffective or absent Preventive Controls
5. Verification of Preventive Controls
6. Preventive Control Records

HACCP

1. Hazard Analysis
2. Critical Control Point identification
3. Establishment of Critical Limits
4. Monitoring Procedures
5. Corrective Actions
6. Record Keeping
7. Verification Procedures

Side by Side Analysis

Preventive Control:

- Written Analysis of Hazards
- Identification of Preventive Controls
- Monitoring of Preventive Controls
- Corrective Actions for Ineffective or absent Preventive Controls
- Verification of Preventive Controls
- Preventive Control Records

Critical Control Point:

- Hazard Analysis
- Critical Control Point identification
- Establishment of Critical Limits**
- Monitoring Procedures
- Corrective Actions
- Record Keeping
- Verification Procedures

Five differences between HACCP and HARPC:

1. HARPC is specifically for FDA production within USDA jurisdiction
2. HARPC encompasses prerequisite programs and SOPs as well as traditional HACCP critical control points
3. HARPC requires a preventive controls qualified individual to develop and apply the food safety system
4. HARPC includes radiological hazards as well as biological, chemical, and physical hazards
5. HARPC re-analysis must be completed every three years

A quick history of HARPC

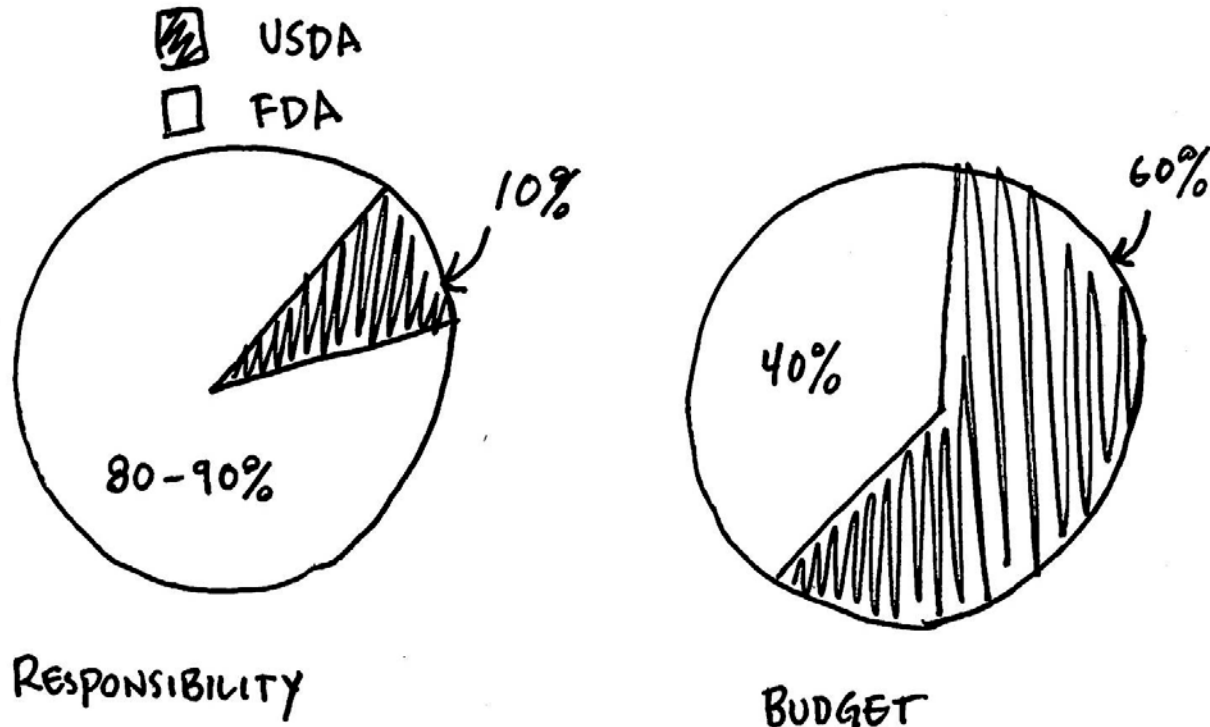
September
17, 2016!



January 4, 2011

- Food Safety Modernization Act
- FDA had to promulgate the actual regulations

An informative chart:



A couple of quick questions:

Would a meat and poultry facility have to comply with HARPC?

How about juice or seafood facility?

What about a food facility based out of Europe?

Answer:

HARPC is specifically for FDA production within United States jurisdiction

Why are fish and juice exempted from HARPC?



Definitions:

Critical Control Point:

A step at which control can be applied and is essential to prevent or eliminate a food safety hazard, or reduce it to an acceptable level.

Preventive Control:

Reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safety of food would employ to significantly minimize or prevent hazards

Definitions:

Critical Control Point:

A step at which control can be applied and is essential to prevent or eliminate a food safety hazard, or reduce it to an acceptable level.

Preventive Control:

Reasonably appropriate **procedures, practices, and processes** that a person knowledgeable about the safety of food would employ to significantly minimize or prevent hazards

A visual depiction:

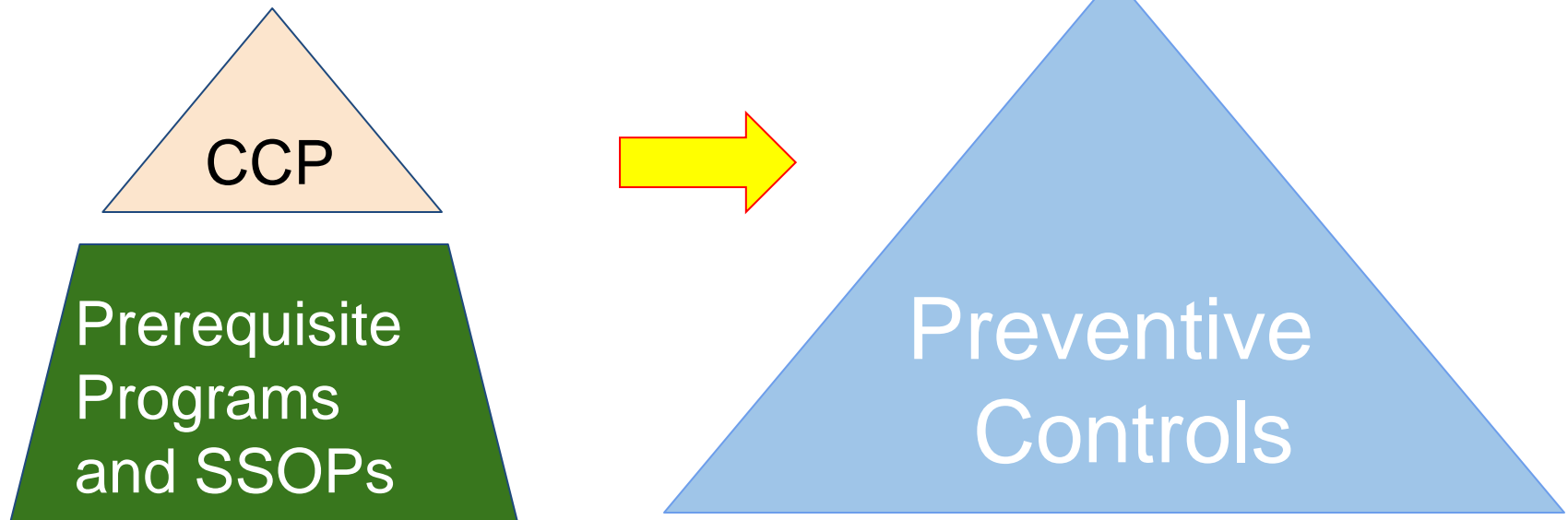
Production process:

CCP



Preventive Controls

Another visual depiction:



Yes, a holistic approach to food safety seems like a good idea.



I agree. CCPs alone might not be enough to prevent a food safety hazard.



Verification and Validation

Validation:

Does what we
are doing really
work?

Verification:

Are we doing
what we say we
are doing?

An interesting tidbit to make things easier:

Production process:

PPC

Preventive Controls

Difference #2

HARPC encompasses prerequisite programs and SOPs as well as traditional HACCP critical control points

What will that mean for critical limits?

- HARPC does not require critical limits for all controls.
- Some preventive controls have monitorable parameters, and some will not.
- The corrective action paradigm will have to shift.

Definitions:

Critical Control Point:

A step at which control can be applied and is essential to prevent or eliminate a food safety hazard, or reduce it to an acceptable level.

Preventive Control:

Reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safety of food would employ to significantly minimize or prevent hazards

Definitions:

Critical Control Point:

A step at which control can be applied and is essential to prevent or eliminate a food safety hazard, or reduce it to an acceptable level.

Passive voice

Preventive Control:

Reasonably appropriate procedures, practices, and processes that **a person knowledgeable about the safety of food would employ** to significantly minimize or prevent hazards

Active voice

Difference #3

HARPC requires a qualified individual

Some implications from the qualified individual clause:

- No HACCP team required
- The training requirement
- Ominous Department of Justice warnings

The HACCP team paradigm

- Requirement as part of the preliminary steps of HACCP.
- Allowed for cross functional input
- Specifically noted that HACCP preparation “should not be left to the sole responsibility of one person.”



Why the move to a qualified individual?

An important note:

- The HACCP team does not have to go away.
- The HACCP team should probably not go away.
- Actually, you should probably keep your HACCP team. It is a good idea.

A couple of bonus questions:

- What role does the preventive controls qualified individual have to have?
- What sort of job experience would a qualified individual have to show?
- Who would they have to show it to?
- What benefit is there to having specialized training?



May I see your certificate please?

The preventive controls qualified individual

- Must be qualified to develop and apply a food safety system.
- Charged with overseeing the validation that preventive controls are capable of controlling identified hazards AND the records review.
- Criteria:
 - Specialized training; or
 - Job experience

Is there anyone else you might have to show your certificate to?

“Government wants to be able to jail executives for food safety violations” - Food Safety News

“Investigators also learned that the (Defendants) had long been aware of their facilities’ Salmonella problem; **knew how to address it** and failed to take steps necessary to prevent contaminated (food products) from entering the marketplace,”

Difference #4

HARPC includes radiological hazards as well as biological, chemical, and physical hazards:

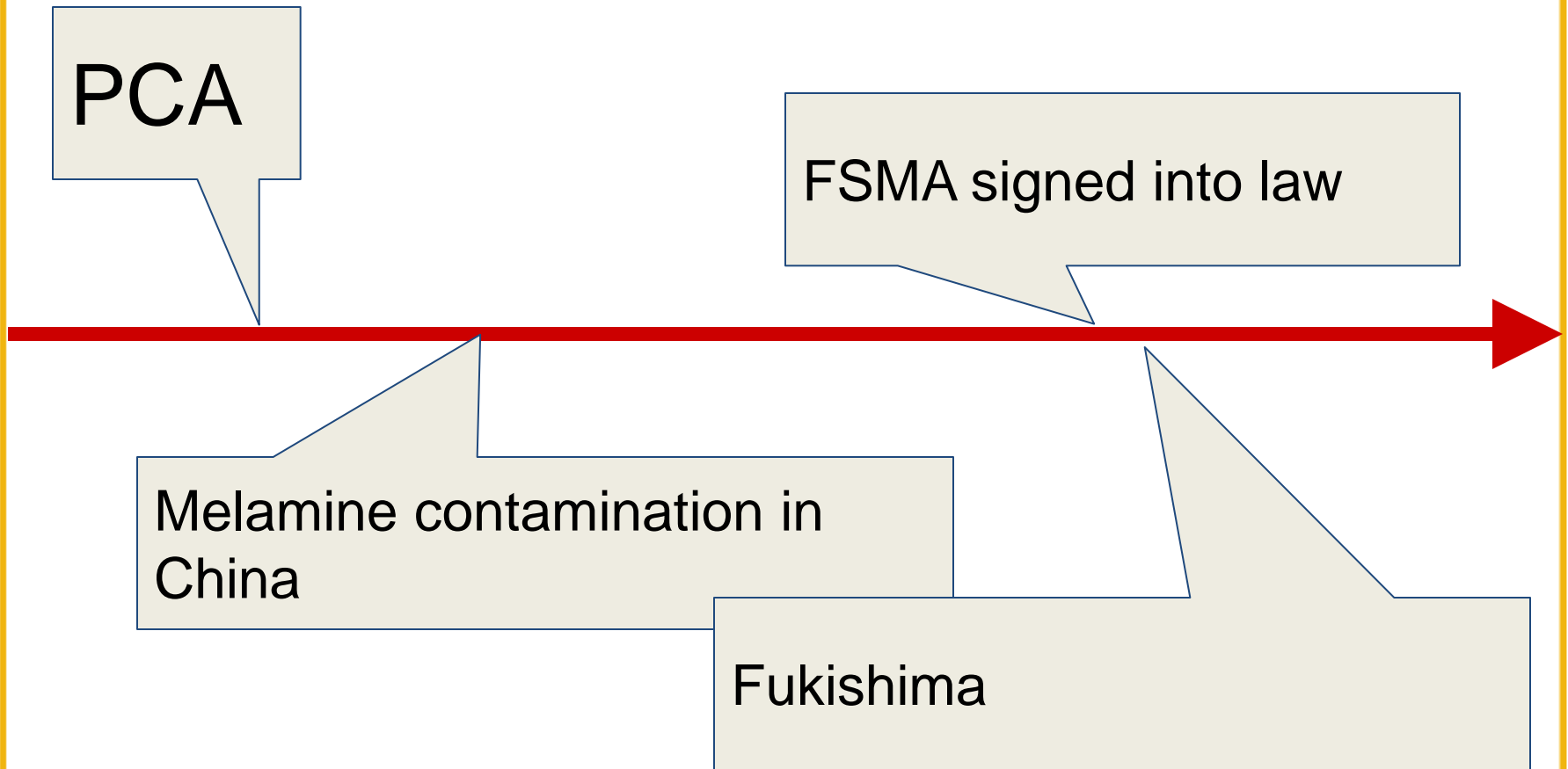


January 4, 2011



March 11, 2011

A timeline of FSMA



Difference #5

HARPC re-analysis must be completed every three years

What are some reasons for increased frequency of reanalysis?

There is more.

- Here are some places where you can go to find out more:
 - FDA Website FSMA
 - <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>
 - Food Safety Preventive Controls Alliance
 - <http://www.iit.edu/ifsh/alliance/>

Any questions?