

Company Action Plan

What Do I Need to Do Now?



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Choices



Choices



Where is it?

Choices

- *Prepare for the worse*



And hope for the best!



What Do I Need to Do Now?

1) Read the rule

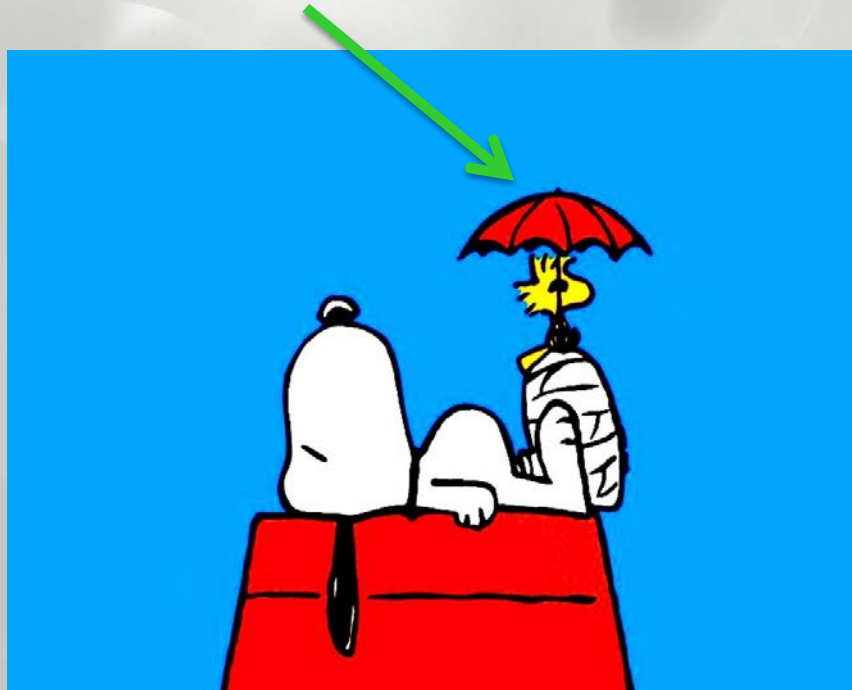
Hint: Start With Pages

56141-56167

28 pages

What Do I Need to Do Now?

2) Determine if you and your customers are qualified for an exemption



What Do I Need to Do Now?

3) Determine your
compliance dates:

- cGMP's and PCs

as well PC's

- Supply Chain

What Do I Need to Do Now?

4) Plan holistically

Recognize the impact of the
6 other rules

Recognize where your
business is in terms of
quality systems

What Do I Need to Do Now?

5) Gain leadership resources and commitment for a cross functional approach.

“I cannot give you a formula for success, but I can give you the formula for failure, which is: try to please everybody.”

Herbert Bayard Swope-(the first and three-time recipient of the Pulitzer Prize for Reporting)

What Do I Need to Do Now?

6) Get Training

if needed

Food Safety Preventative Controls
Alliance

What Do I Need to Do Now?

7) Ensure you understand all the applicable definitions.

Review comments

What Do I Need to Do Now?

Adequate- means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Subpart B CGMP's) 170.80c)1(a) wood discussion

What Do I Need to Do Now?

Environmental Pathogen- FDA Comments

"We have not included the indicator organism *Listeria* spp. as an example of an environmental pathogen, whether in the regulatory text, in the preamble of this document, or in guidance. Although we agree that *Listeria* spp. is an appropriate indicator organism when conducting verification testing for sanitation controls, the definition in question is for a pathogen, not for indicators of a pathogen."

What Do I Need to Do Now?

Economically Motivated Adulteration:

As part of preventative controls
food safety plan.

- is *Food Safety* focused

What Do I Need to Do Now?

8) Use a Checklist and Do a Gap assessment against the requirements.

B 117.10—Personnel	Current Good Manufacturing Practice.	
B 117.10(a)	A. Management Responsibility for Requirements Applicable to Personnel	
B 117.10(b)	Disease Control-Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel must be instructed to report such health conditions to their supervisors.	
B 117.10(b)(1)	Cleanliness-All persons working in direct contact with food, food-contact surfaces, and food- packaging materials must conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of food. The methods for maintaining leanness include:	
B 117.10(b)(2)	Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of food, foodcontact surfaces, or food- packaging materials.	
B 117.10(b)(3)	Maintaining adequate personal cleanliness	
B 117.10(b)(4)	Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate handwashing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.	

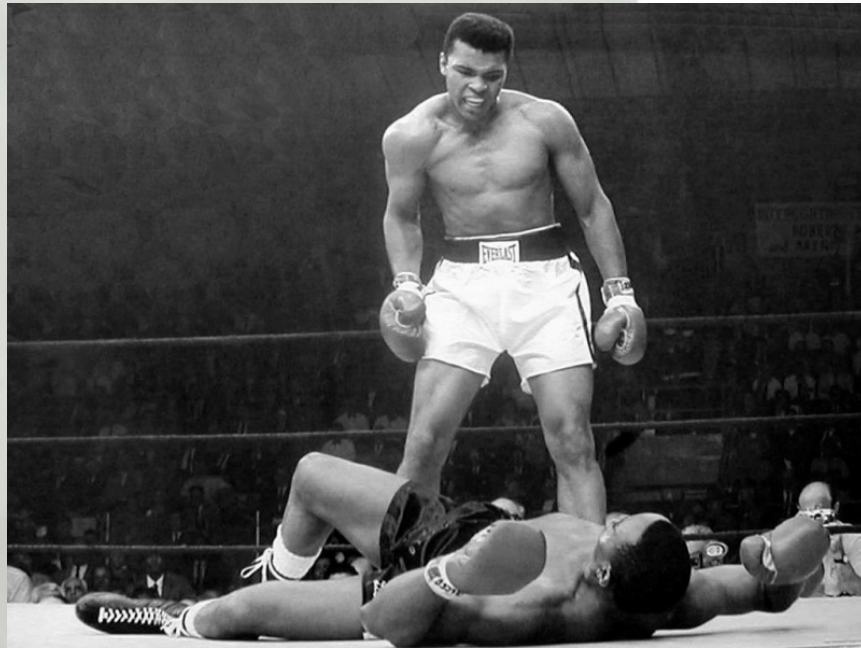
What Do I Need to Do Now?

8) Recognize that when FDA starts doing inspections where they may look first

- In the office
 - Food Safety Plan
 - Corrective Actions & Corrections log

What Do I Need to Do Now?

9) Recognize that while the Supply Chain seems to be a small section, it has a big punch.



What Do I Need to Do Now?

Supply-chain program must include:

- 1) Using approved suppliers as required by § 117.420;
- 2) Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by § 117.425;
- (3) Conducting supplier verification activities as required by §§ 117.430 and 117.435;
- (4) Documenting supplier verification activities as required by § 117.475; and
- (5) When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier

What Do I Need to Do Now?

10) To that end, if you are not third party audited already, and make anything other than a low risk food-

Get Certified

What Do I Need to Do Now?

11) Documentation Focus:
Who, What, When,.....

Why,

*You did it how you
documented it.*

What Do I Need to Do Now?

