



Washington  
State Department of  
Agriculture

# Washington State cGMP & PC Observations From The Field.



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# Thank You for Your Work So Far!



- We understand that the cGMP and PC rules are still new to many in the animal food world. As an inspector, I would like to thank you all in industry for putting in the time and effort to do your best to comply with these regulations!
- In this portion of the training we will discuss some of the objectionable conditions and confusions with the regulations that the field staff are discovering throughout the animal food industry.



# Compliance Dates



Key Dates	Preventive Controls Animal Food (PCAF)
Sept. 19, 2016	<ul style="list-style-type: none"><li>• Large business cGMP are to be in compliance</li></ul>
Sept. 18, 2017	<ul style="list-style-type: none"><li>• Small business cGMP are to be in compliance</li><li>• Large business PC are to be in compliance</li></ul>
Sept. 17, 2018	<ul style="list-style-type: none"><li>• Very Small business cGMP are to be in compliance</li><li>• Small business PC are to be in compliance</li></ul>
Sept. 17, 2019	<ul style="list-style-type: none"><li>• Very Small business PC are to be in compliance</li></ul>

# PCQI vs QI.



## ***Preventive Controls Qualified Individual***

- “a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.” -21 CFR 507.3

## ***Qualified Individual***

- “a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.” -21 CFR 507.3

# Employee Training Records



## What is Required?

21 CFR 507. 7. 4

- (1) Receive training in the principles of animal food hygiene and animal food safety, including the importance of employee health and personal hygiene, as appropriate to the animal food, the facility and the individual's assigned duties.
- (2) Records that document training required by paragraph (b)(2) of this section must be established and maintained and are subject to the recordkeeping requirements in subpart F of this part.

# Employee Training Records



## Validation of Qualified Individuals?

What documentation do you create/maintain to validate that employees are:

- “qualified individual as that term is defined in 507.3, i.e., have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold safe animal food as appropriate to the individual's assigned duties.”
- This maybe different than your Division of Occupational Safety & Health (DOSH) training records.

# Pest Control



507.17 (c) - The plant must protect animal food stored outdoors in bulk from contamination by any effective means.

## Emphasis on Effective:

- Hiring an outside company does not absolve the firm from responsibility.
- Firm is responsible to check for pests regularly and adjust pest control practices as needed.
- Plant grounds must be maintained to eliminate harborage.



# Components of a Food Safety Plan.



## For firms subject to subpart C

1. The written hazard analysis as required by 507.33(a)(2);
2. The written preventive controls - 507.34(b);
3. The written supply-chain program, if elected Subpart E
4. The written recall plan - 507.38(a)(1);
5. The written procedures for monitoring the implementation of the preventive controls - 507.40(a);
6. The written corrective action procedures - 507.42(a)(1);
7. The written verification procedures - 507.49(b).

# HACCP or Food Safety Plan?



## Key Differences:

- Hazard analysis: With HACCP plans, biological, chemical, and physical hazards must be identified; for Food Safety Plans (FSPs), radiological hazards and economically motivated adulteration must also be considered.
- Preventive Controls: While HACCP plans only identify CCPs for processes, FSPs call for process CCPs as well as controls at points other than CCPs.
- Records: Records must be maintained for process controls in HACCP plans, but with FSPs, records should be kept for all preventive controls.
- Monitoring: HACCP plans do not require monitoring, but FSPs do. Specifically, monitoring must be done after any hazard requiring a preventive control has been identified.

# Get to Know Your Inspector.



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