

Food Safety Modernization Act cGMP, HA, and Risk-Based PC for Foods for Animals

Short Training for Small Businesses
Washington State Department of Agriculture
May 14, 2020

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Do you manufacture, process, pack, or hold animal food?

- Raw materials/Ingredients
- Complete feeds
- Human Food By-Products
- Livestock feed
- Pet Food
- Treats/Supplements
- Wild Animals



Are you a farm?

- ✓ Growing Crops
- ✓ Harvesting Crops
- ✓ Raising Animals
- ✓ M/P/P/H food for animals on farm



21 CFR 1.227

Are you any of the following?

- Transport vehicle
- Private residence
- Non-bottled water collector and distributor
- USDA FSIS establishment (sole jurisdiction)
- Retail food establishment
- Restaurant (e.g., pet shelter, kennel, vet)

Are you a registered animal food facility?



- Exempt facilities (e.g., farms)
- Biennial
- Online
- Free
- Draft GFI: [Questions and Answers Regarding Food Facility Registration \(Seventh Edition\)](#)
- * Qualified Facility
 - 3942b

Registration of Food Facilities and Other Submissions

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FDA Industry Systems

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[Online Registration of Food Facilities Guides and Tutorials](#)

Are you a Qualified Facility?

- Sales and market value of food
- \$2.5 million three year average
 - [FSMA Inflation Adjusted Cut Offs](#)
- [GFI: Determination of Status as a Qualified Facility](#)
- Attestation
 - Form FDA 3942b



Does your facility perform these activities similar to farms?

- Farm-Related Activities Conducted on Nut Hulls and Shells for Animal Food
- Solely Engaged in Packing, Packaging, and/or Holding Activities Conducted on Non-Produce Raw Agricultural Commodities, such as grains and oilseeds
- Qualify as Secondary Activities Farms Except for the Ownership
- Solely Engaged in the Ginning of Cotton
- Solely Engaged in Conditioning Seed for Use in Animal Food
- Making Silage Food for Animals

GFI: [Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs](#)

Is your Animal Food a Human Food By-Product?

Does your establishment have to register as a human food facility?
(and in compliance with 21 CFR part 117)

Yes

Streamlined requirements in
507.1(d) or 507.12 apply.
See next slide.

No

Human food establishments that don't have to
register as a food facility are exempt from 21 CFR
part 507.

What activities are you performing with your human food by-products?



No further M/P

Only subject to the limited holding and distribution CGMPs in 21 CFR 507.28/117.95 (Not subject to other CGMP or PC requirements)

Certain M/P Activities

Subject to CGMPs (21 CFR part 117 or 507)
Enforcement discretion for PC requirements

All other M/P Activities

Subject to CGMPs & PCs (21 CFR part 117 or 507)
Food safety plan should address hazards associated with the animal food after separation from the human food

If you have reached this point you...

- Manufacture, process, pack or hold animal food
- Are subject to registration
- Are subject to CGMPS and PCs*

Four blue water droplets of varying sizes and orientations, arranged in a loose cluster on the left side of the slide.

Next step, Food Safety Plan

Do you have a Preventive Controls Qualified Individual?

- Food Safety Plan
- Training or Job Experience



FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE



Are you following the CGMPs?

- Housekeeping requirements
- GFI#235: Current Good Manufacturing Practice Requirements for Food for Animals
- Separate from 21 CFR 225

Subpart B—Current Good Manufacturing Practice	
§507.14	Personnel.
§507.17	Plant and grounds.
§507.19	Sanitation.
§507.20	Water supply and plumbing.
§507.22	Equipment and utensils.
§507.25	Plant operations.
§507.27	Holding and distribution.
§507.28	Holding and distribution of human food by-pro

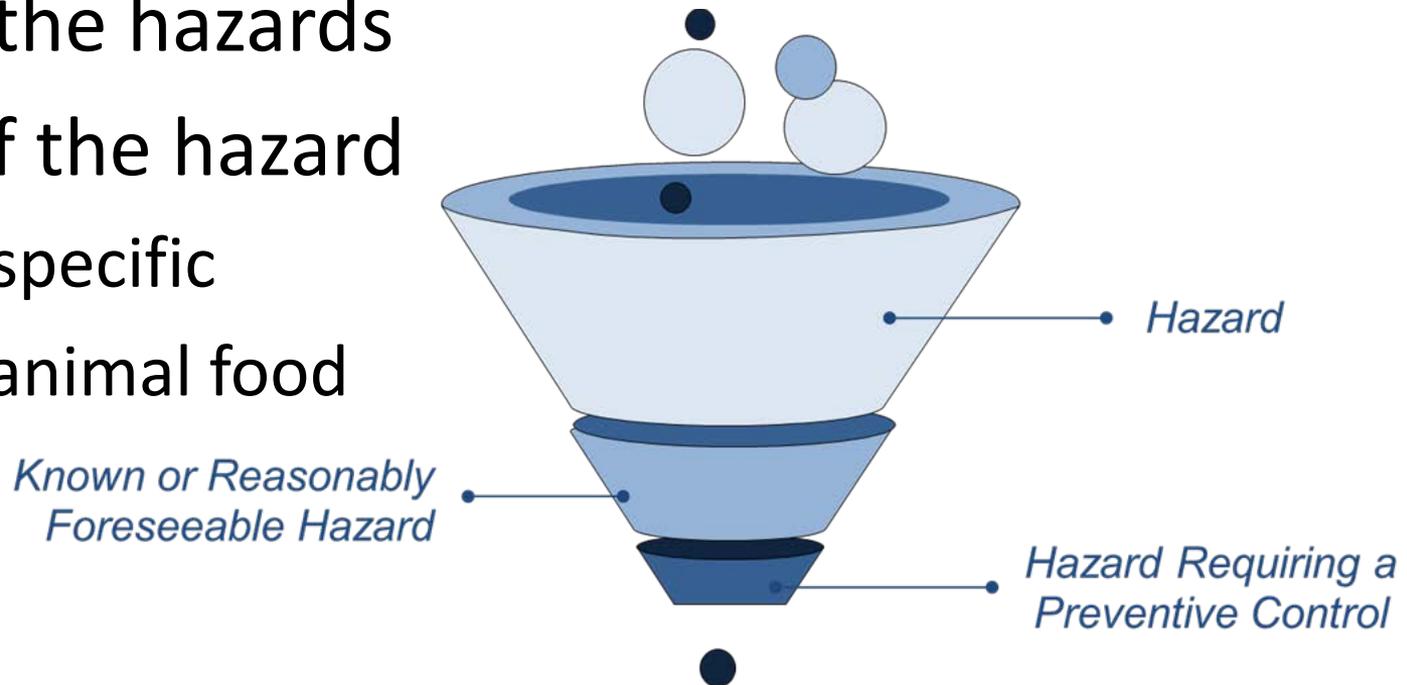
Do you know your Hazards?

- Biological
- Chemical
- Physical
- Ingredient Related
- Process Related
- Facility Related

Draft GFI #245: Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

Have you identified your known or reasonably foreseeable hazards?

- Evaluate the hazards
- History of the hazard
 - Facility specific
 - Similar animal food



Have you evaluated the severity of your known or reasonably foreseeable hazards?

- Susceptibility of species to illness or injury
- Susceptibility of humans to illness or injury
 - Handling
 - Consumption
- Magnitude and duration of the illness or injury
- Secondary Problems

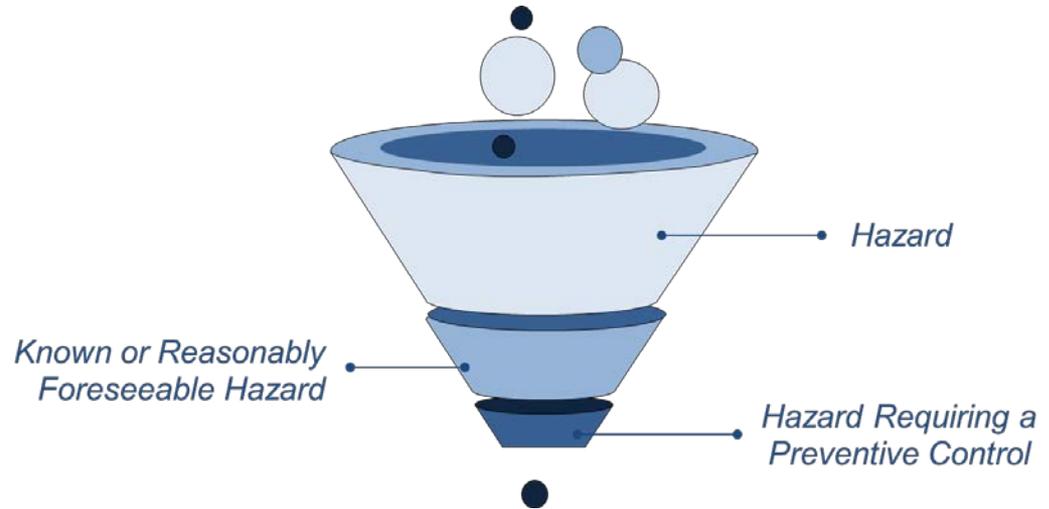


Have you evaluated the probability of your known or reasonably foreseeable hazards?

- Frequency of association
 - Animal food
 - Facility
- Transport and storage conditions
- Pre-requisite programs

Do you know your Hazards Requiring a Preventive Control?

- Severity + Probability Assessment





Do you have a Hazard Requiring a Preventive Control?

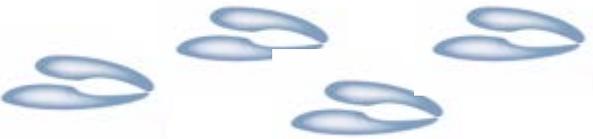


- Complete
- Signed
- Reanalysis

- Reanalysis
 - Every 3 years
 - Changes in facility
 - New hazards
 - Food safety problem
 - FDA

If you have reached this point you...

- Manufacture, process, pack or hold animal food
- Are subject to registration
- Are subject to CGMPS and PCs*
- Have at least one hazard requiring a preventive control

A decorative graphic consisting of several overlapping, light blue, oval shapes arranged in a cluster on the left side of the slide.

Next step, control the hazard

Who is Going to Control the Hazard Requiring a Preventive Control?

- Supply Chain Applied Control
- Preventive Control
- Commercial Customer Provisions

Are you using a Supply Chain Applied Control?



- Approving suppliers
- Implementing written receiving procedures
- Determining, conducting, and documenting supplier verification activities

Supplier means the establishment that manufactures/processes the animal food, raises the animal, or grows the food that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a *de minimis* nature.



Are you Importing a Food with a Hazard Requiring a Preventive Control?

- Foreign Supplier Verification Program rule
- Manufacturer/Processor
 - Deemed in compliance if you have established and implemented a supply-chain program under PCs

**Draft GFI: Foreign Supplier Verification
Programs for Importers of Food for Humans
and Animals**

Are you only storing unexposed animal food?



CGMP (Subpart B) applies

Is a time/temperature control required?



Subparts C & E do not apply

21 CFR 507.10



Modified PC Requirements

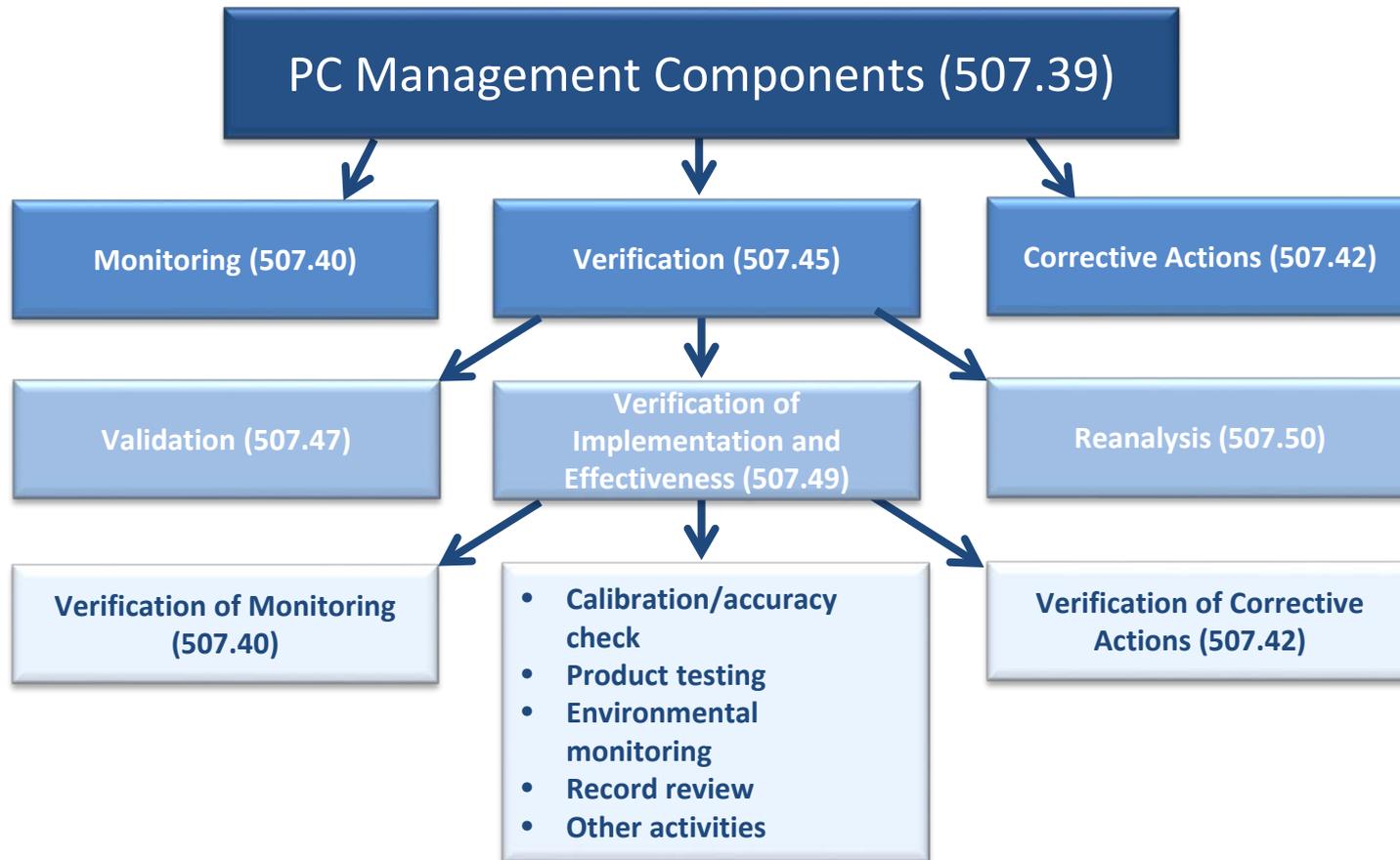
21 CFR 507.51

Are you applying a Preventive Control?



- Process Control
- Sanitation Control
- Other Control

Are you applying a Preventive Control?



Do you have a recall plan?

- Recall plan must establish procedures for:
 - Directly notifying customers about recall
 - Notifying the public when appropriate
 - Conducting effectiveness checks
 - Disposing of recalled animal food
- Assign responsibility for all procedures in the recall plan.

Are you relying on your commercial customer to control a hazard?

- Hazard will be controlled by manufacturer/processor
- Disclosure

21 CFR 507.36

Draft GFI: Describing a Hazard That Needs Control in Documents Accompanying the Food, as Required by Four Rules Implementing the FDA Food Safety Modernization Act

Still have questions?

- www.fda.gov/fsma
- FSMA Technical Assistance Network (TAN)
 - Portal on website →

Food Safety Modernization Act (FSMA)
Frequently Asked Questions on FSMA
FSMA Rules & Guidance for Industry
What's New in FSMA
FSMA Training
FSMA Technical Assistance Network (TAN)

Food Safety Modernization Act (FSMA)

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Protecting Human and Animal Health**

Thank you!

