



Our Industry. Our Passion. Our Voice.

Legislative Update Northeast Agribusiness and Feed Alliance

Louise Calderwood

June 23, 2022



VOICE



REPRESENTATION



EXPERTISE



ENGAGEMENT

AFIA L&R Staff Contact Info



Louise Calderwood
Director, Regulatory Affairs
lcaldерwood@afia.org
(703) 558-3568



Kori Chung
Public Policy and Certification Specialist
kchung@afia.org
(703) 666-8862



Paul Davis
Director, Quality, Animal Food Safety & Edu.
pdavis@afia.org
(703) 650-0146



Mallory Gaines
Director, Market Access and Trade Policy
mgaines@afia.org
(703) 558-3569



Gary Huddleston
Director, Feed Manufacturing and Regulatory Affairs
ghuddleston@afia.org
(703) 666-8854



Gina Tumbarello
Senior Director, International Policy and Trade
gtumbarello@afia.org
(703) 558-3561



Leah Wilkinson
Vice President, Public Policy and Education
lwilkinson@afia.org
(703) 558-3560

Our Industry. Our Passion. Our Voice.





Our Industry. Our Passion. Our Voice.

AFIA Priorities 2022-2023



VOICE



REPRESENTATION



EXPERTISE



ENGAGEMENT

AFIA 2022-23 Policy Priorities

**Improvement
of the Business
Climate**



**Sustainability &
Climate Policy**



**Availability &
Cost Effectiveness
of Ingredients**



**Feed &
Food Safety**



**Health,
Safety & the
Environment**



**Global Market
Access &
Competitiveness**



Our Industry. Our Passion. Our Voice.



Lot's going on!

- **Trade**
- **FDA Inspections**
- **EPA/OSHA**
- **African swine fever**
- **AAFCO**
- **FDA ingredient claims**





Our Industry. Our Passion. Our Voice.

Trade Update



VOICE



REPRESENTATION



EXPERTISE



ENGAGEMENT

Animal Food Industry Supports Trade

\$7.5B* = total U.S. animal food exports including:

- **\$5.5B** = feed & feed ingredients
- **\$2.0B** = pet food products

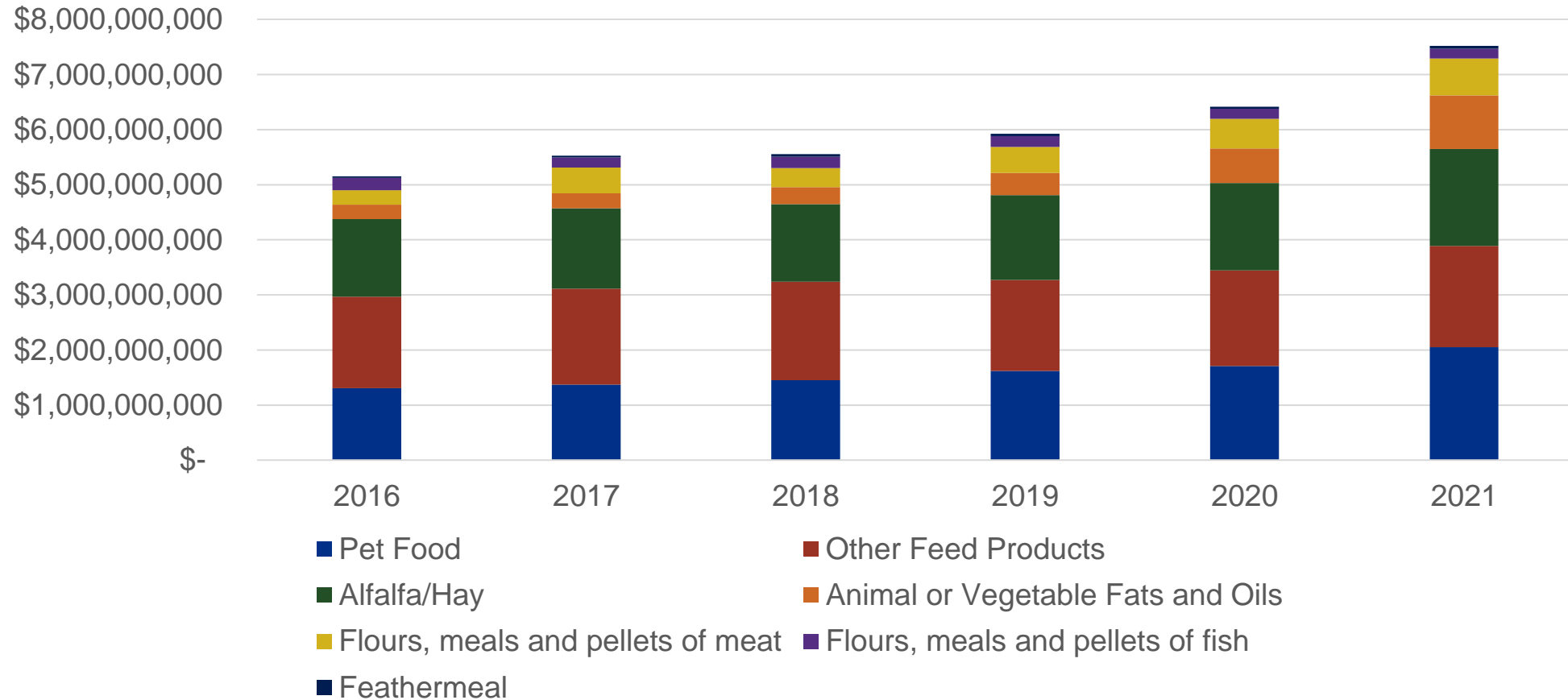


**Total excludes bulk commodities, soybean meal and corn co-products*

Our Industry. Our Passion. Our Voice.



US Animal Food Exports



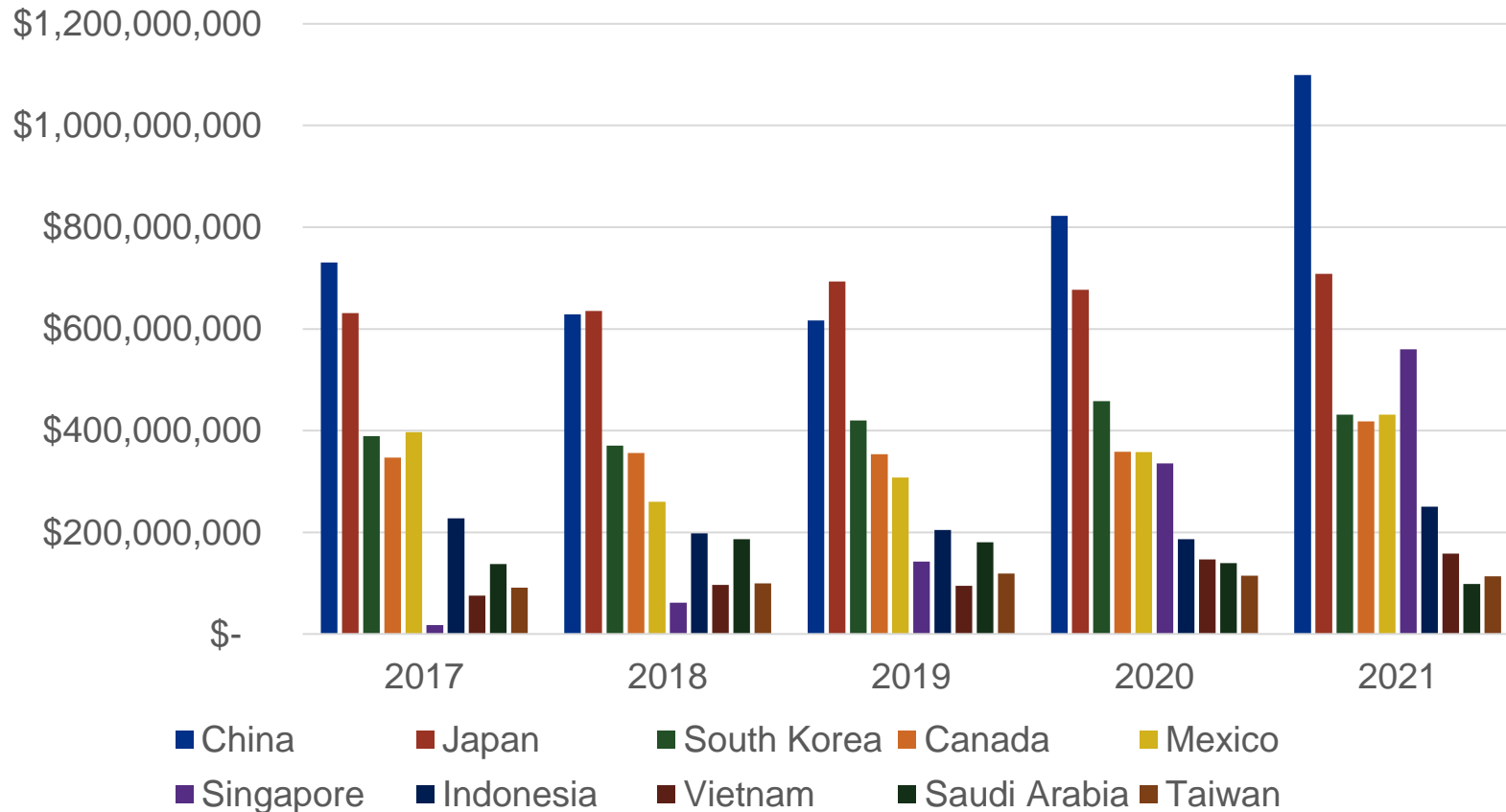
Data Source: Trade Data Monitor

Our Industry. Our Passion. Our Voice.



US Animal Feed Top 10 Export Markets

* data excludes pet food, soybean meal and corn co-products



- Top 3 markets: China, Japan, Singapore
- China up 33% from 2020
- Top commodities to China: alfalfa/hay & other feed products

Data Source: Trade Data Monitor

Our Industry. Our Passion. Our Voice.



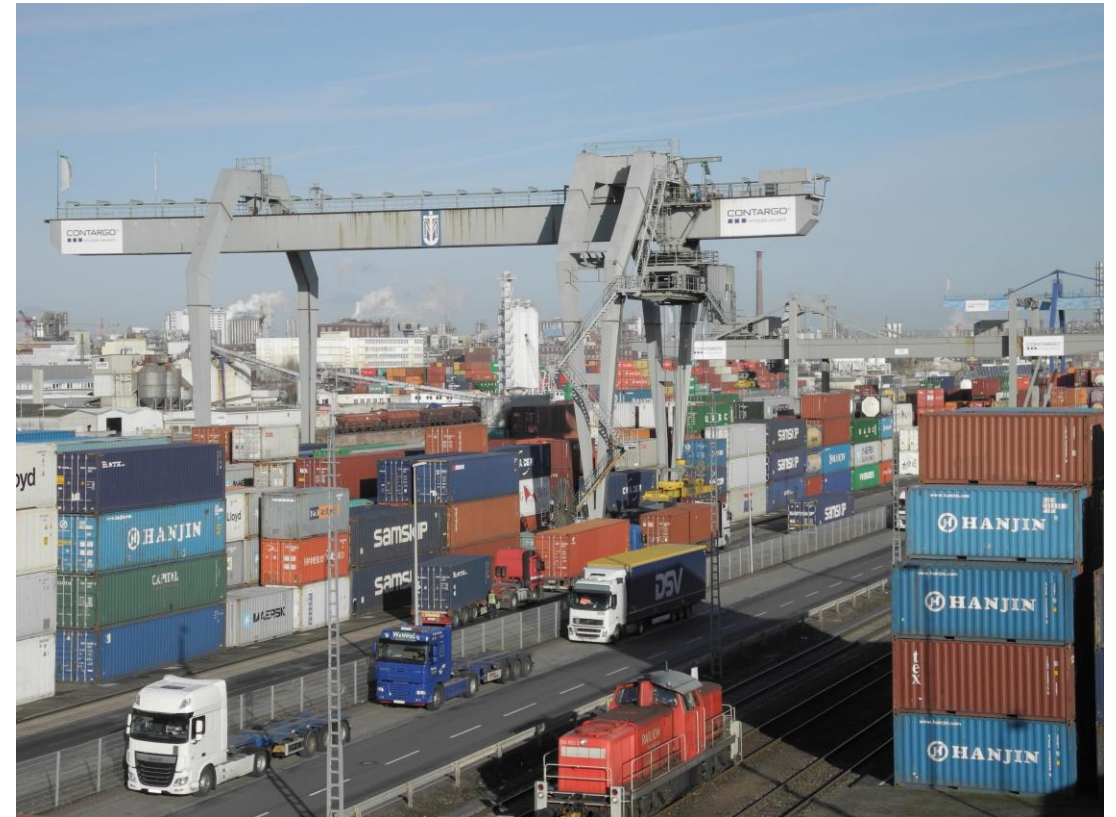
Port/Export Container Issue

- Increased cost of Asian-based imports
- Increased fees
- Inability to export
- Lack of containers
- Current lock-downs in China...



Port/Export Container Actions

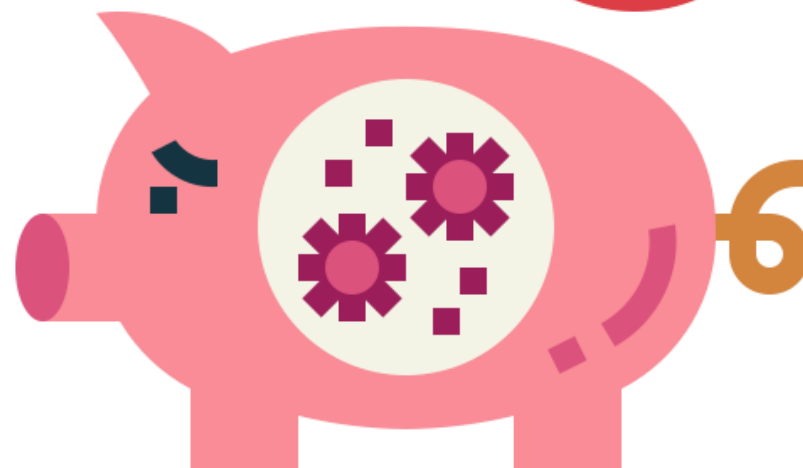
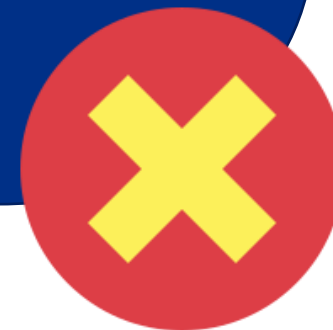
- Infrastructure package
 - funding for port upgrades
- Ocean Shipping Reform Act
- Still needed:
 - more port infrastructure
 - collaboration on the intermodal system



Export Concerns

Almost all feed products with animal-derived ingredient are exported on a VS 16-4.

DID YOU
KNOW?



Does your product have animal origin ingredients in it?

YES

Do you export your product?

YES

Does your product have porcine-derived ingredients?

YES

NO

Export of your product will be affected in the event of an ASF outbreak on the continental U.S.

What is AFIA doing



- APHIS, FAS and USTR talks
 - On-going meetings with USDA APHIS
- Industry coordination and collaboration
 - PFI, NARA, U.S. Hide, Skin and Leather Association, and North American Spray Dried Blood & Plasma Producers
- Delivering Hill messaging leveraging the issues of supply chain, resilience and food security.



Our Industry. Our Passion. Our Voice.

FDA/State Inspections Update



VOICE



REPRESENTATION

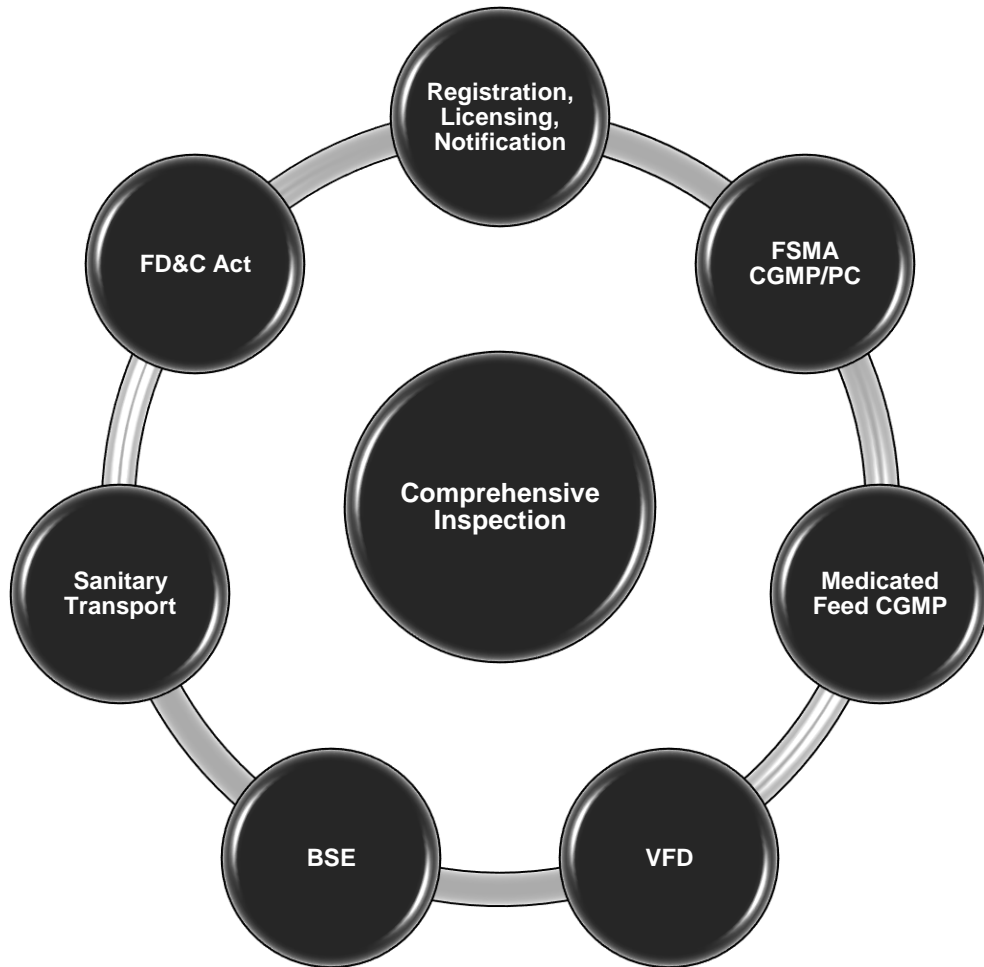


EXPERTISE



ENGAGEMENT

Comprehensive Inspection



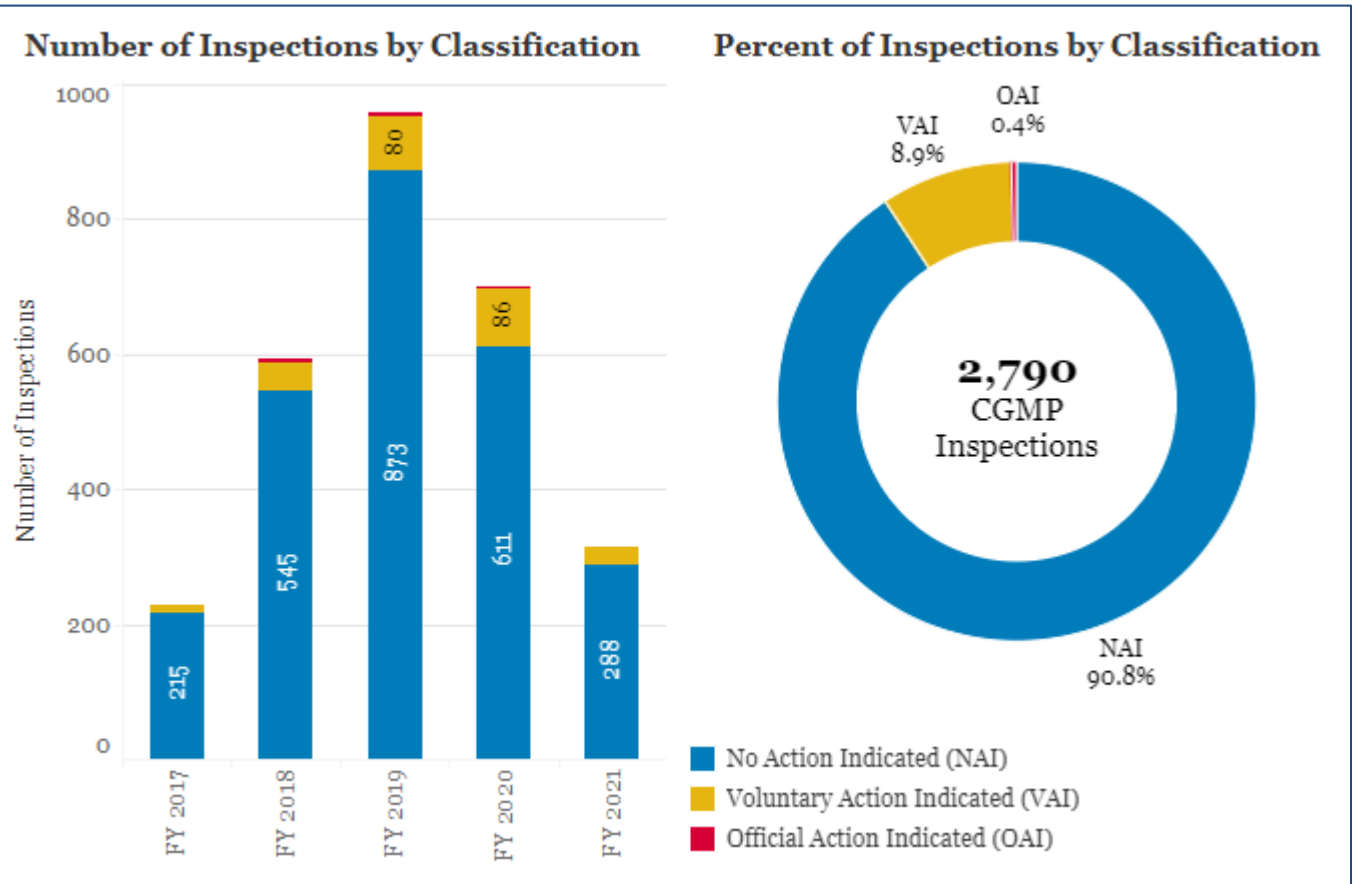
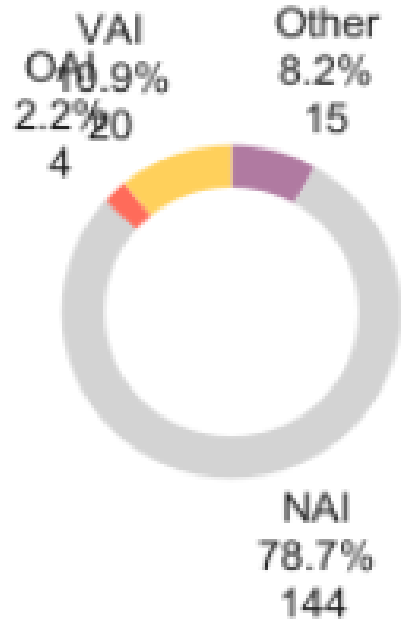
Our Industry. Our Passion. Our Voice.

FSMA Metrics – CGMP Inspections



Historical FDA and State CGMP Inspections

FY22 FDA and State CGMP Inspections

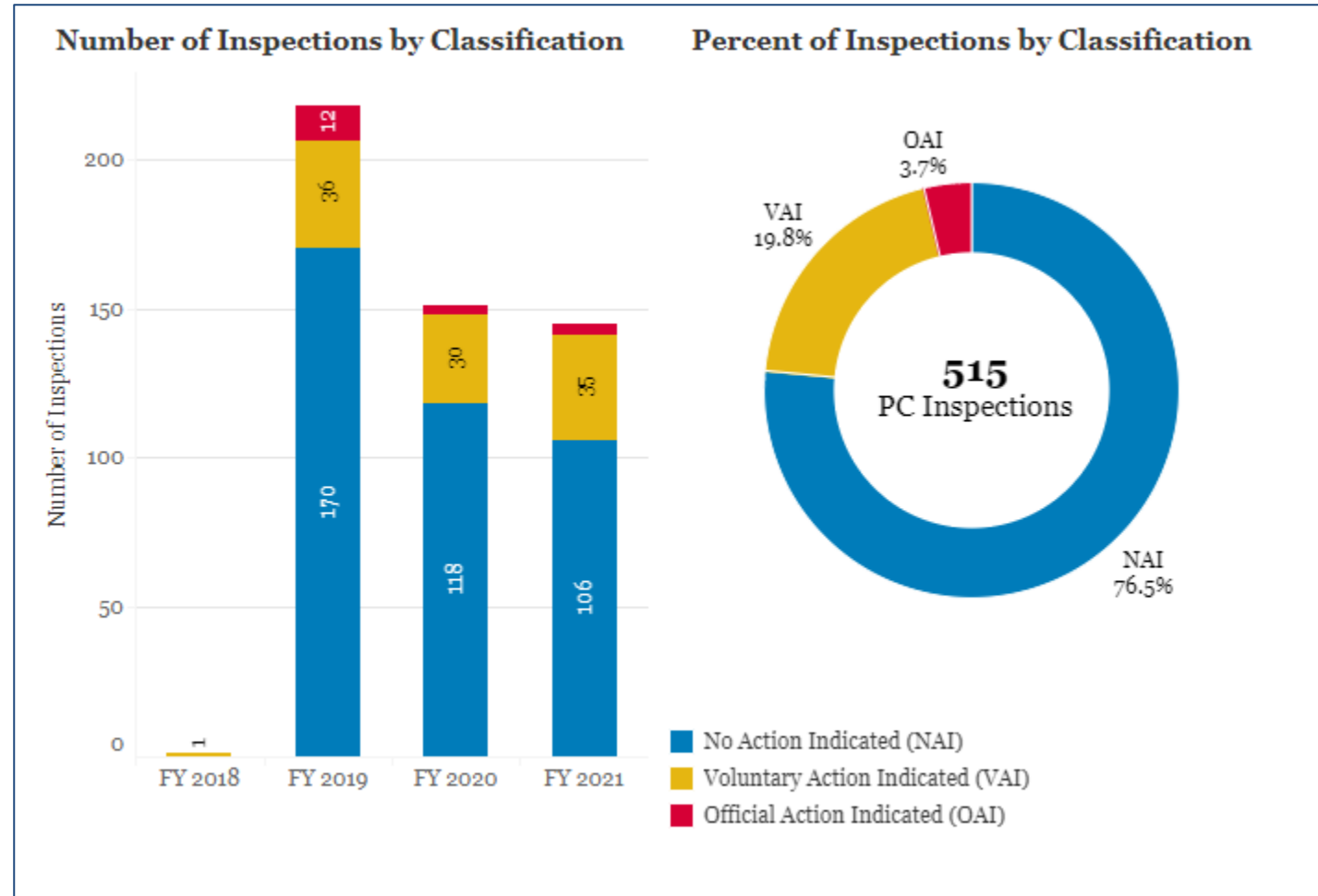
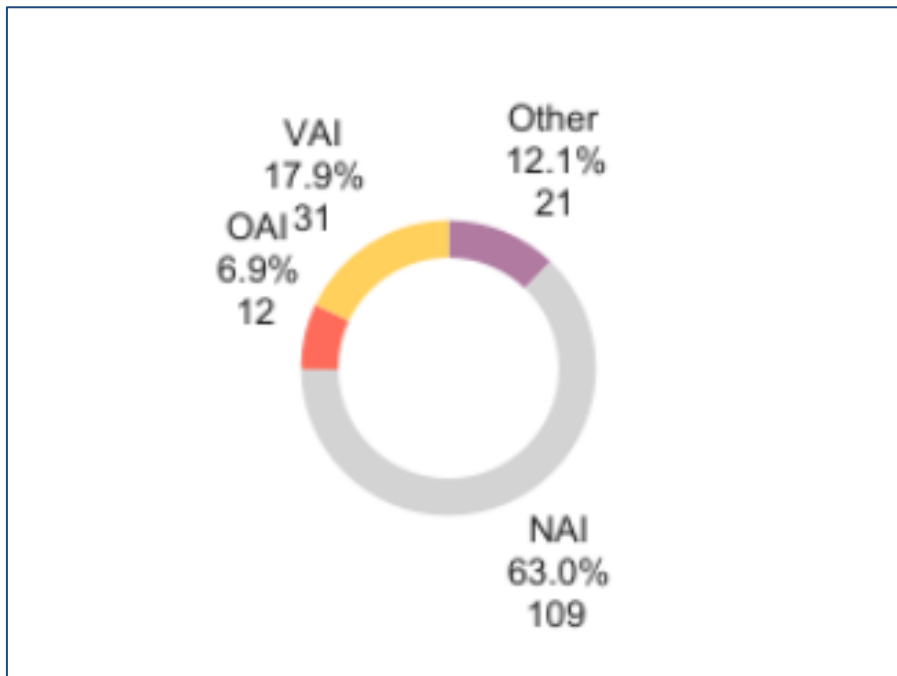


FSMA Metrics – PC Inspections



Historical FDA and State PC Inspections

FY22 FDA and State PC Inspections



Concerning Food Safety Observations

- CGMP Observations
 - Evaluation of raw materials/ingredients
 - Take adequate precautions to ensure plant operations do not result in contaminated animal food



Concerning Food Safety Observations

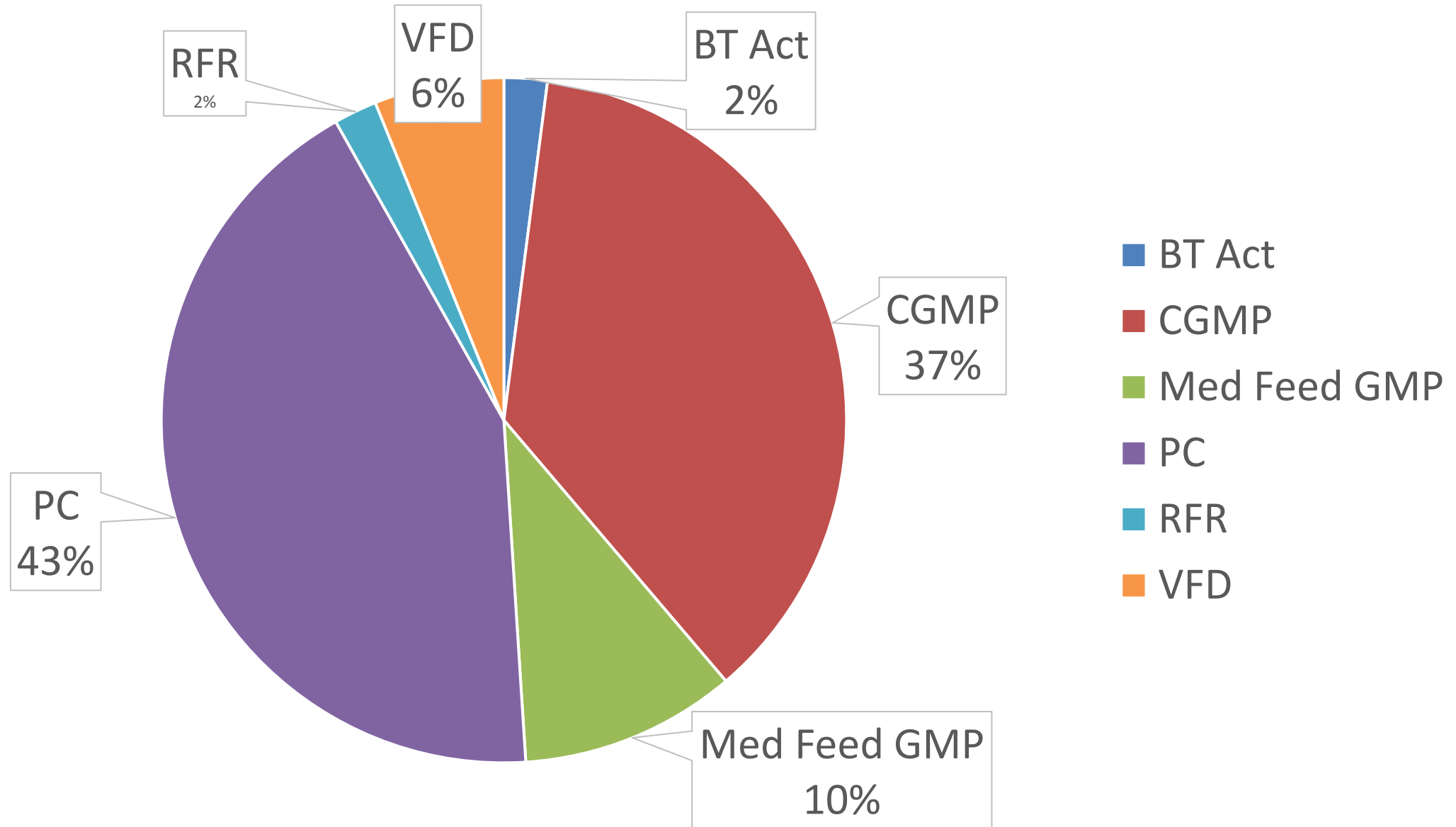
- PC Observations
 - Failure to identify/implement PCs
 - Includes failures in design and implementation of pre-requisite programs
 - No written Food Safety Plan
 - No written hazard analysis or evaluation of each known or reasonably foreseeable hazard



Common Non-FSMA Citations

- Medicated Feed – Drug Components
 - Not properly identifying, storing, handling, or controlling drugs to maintain their integrity and identity (licensed medicated feed mills)
 - Drug components are not identified and stored in a manner such that their identity, strength, quality and purity will be maintained (non-licensed feed mills)
- Medicated Feed – Assays/Investigations
 - Not conducting three periodic assays (licensed medicated feed mills)
 - Not conducting an investigation when assays of drug components do not meet permissible drug levels (non-licensed feed mills)
- VFD
 - Failure to file a VFD Distributor Notification with FDA

Citations by Requirements





Our Industry. Our Passion. Our Voice.

OSHA and EPA Update



VOICE



REPRESENTATION



EXPERTISE



ENGAGEMENT

DOL's Early Priorities

- Increased budget
- Increase in inspections
- Increased news releases of inspection results
- Continue to seek maximum penalties



OSHA Watch List

- Powered Industrial Trucks Rule Update
- Lockout/Tagout Rule Update
- Potential Infectious Disease Standard
- Potential Heat Illness Prevention Standard
- Potential Emergency Response Preparedness Rule Update
- Occupational Injury and Illness Recordkeeping Regulation Update



EPA's Recent Activities Affecting Our Industry



- Rodenticides
- Formaldehyde
- Chlorpyrifos



Rodenticides

- Currently undergoing normal 15-year registration review process
- Expected proposed interim decision delayed until June
- AFIA has had conversations with the EPA, FDA and USDA about the issue
- Very good possibility that the bulk forms of these products may become “restricted use” pesticides

FGARs

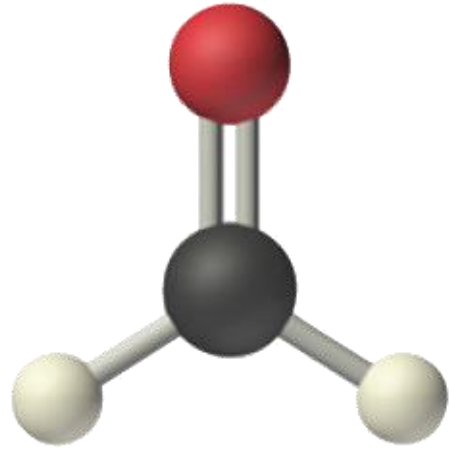
Chloropacinone
Diphacinone
Warfarin

SGARs

Brodifacoum
Bromadiolone
Difenacoum
Difethialone

Acute Toxicants

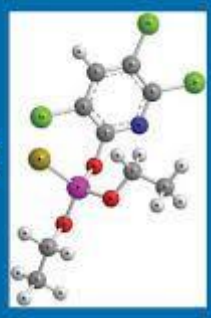
Acrolein, Bromethalin, Potassium Nitrate,
Sodium Nitrate, Strychnine, Zinc
Phosphate



Formaldehyde,
 CH_2O

- **Three on-going risk assessments of Formaldehyde by EPA**
 - Office of Pesticide Programs (OPP)
 - Office of Pollution Prevention & Toxics (OPPT)
 - Integrated Risk Information System (IRIS)
- **Classified as a human carcinogen**
- **Used in animal food as an antimicrobial**
 - Effective tool for controlling *salmonella* in feed
 - Could be an effective tool against ASF
- **AFIA is urging EPA to “follow the science”**

CHLORPYRIFOS



- Organophosphate insecticide used on many crops
- Used primarily to control foliage and soil-borne insect pests
- EPA issued a final rule to revoke all tolerances of chlorpyrifos in food effective Feb. 28, 2022
- Food containing any residue of chlorpyrifos after Feb. 28 would be considered adulterated
- FDA will exercise “enforcement discretion” for products containing residues as long as the chlorpyrifos was applied before Feb. 28



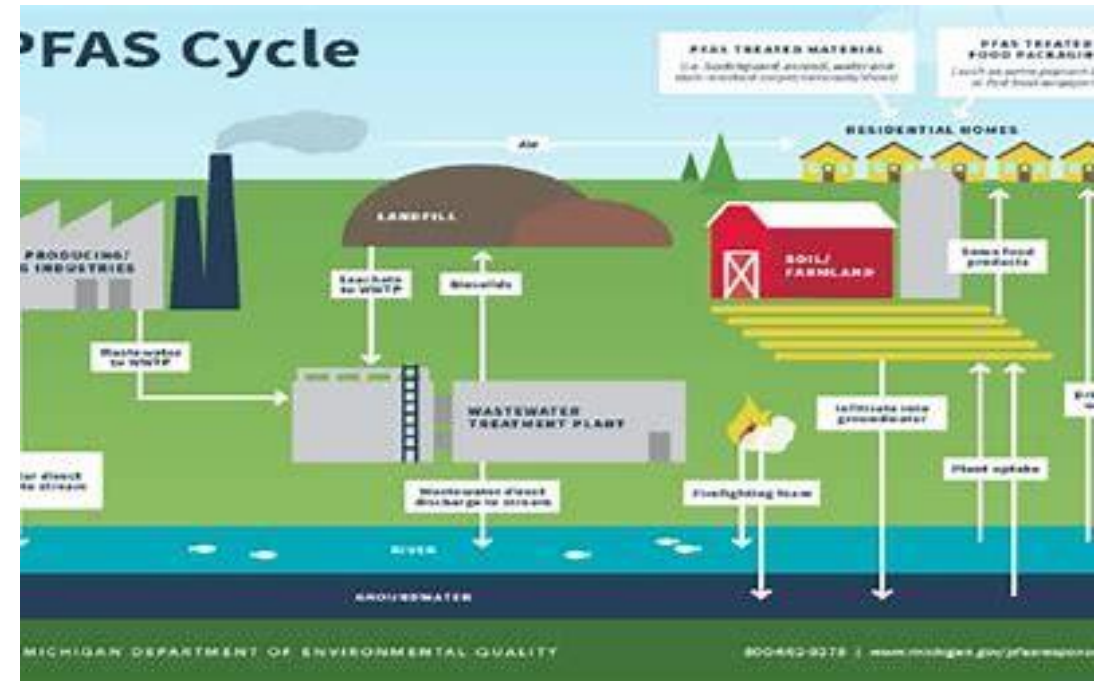
EPA's Strategic Roadmap for PFAS is centered on three guiding strategies:

- **Accelerate the cleanup of PFAS contamination**
- **Leverage authorities to take action now to restrict PFAS chemicals from being released into the environment**
- **Increase investments in research**

www.epa.gov

PFAS-State by State by State by State

- Maine- federal “observation study”-Soil, water, food
 - Every citizen can submit 1 soil sample
- Vermont- heightened attention on soil
- New York-still focused on water





Our Industry. Our Passion. Our Voice.

African Swine Fever Update



VOICE



REPRESENTATION



EXPERTISE



ENGAGEMENT

African Swine Fever

It's easy to spread ASF—without even knowing it. The virus can stay on clothing and equipment and survive for months in pork products. Be aware of these potential pathways and consider them when creating or updating biosecurity plans.

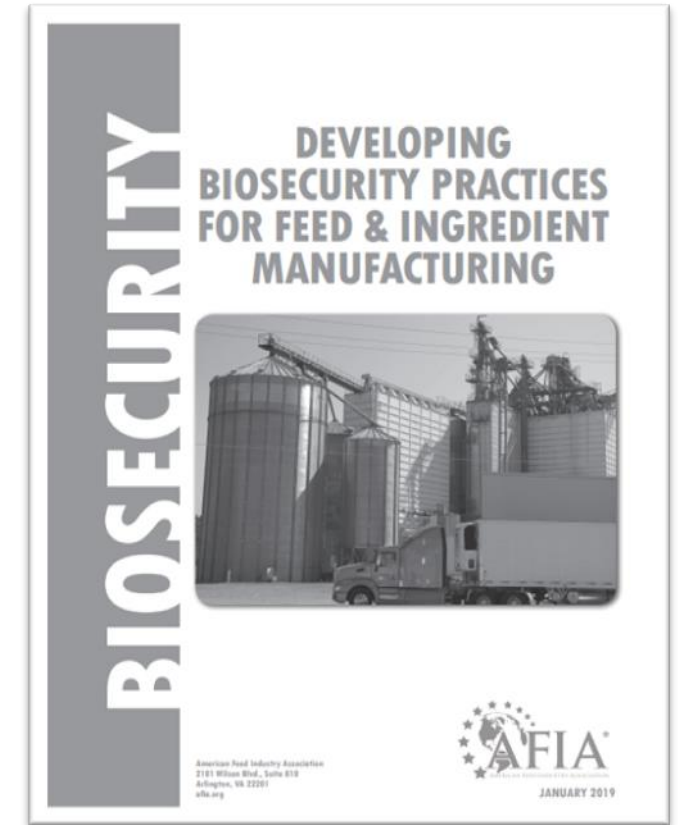


Our Industry. Our Passion. Our Voice.



Biosecurity

- All species, various disease concerns
- Facility specific
 - Intended species, disease risk, potential vectors/fomites, likelihood
- Measures to eliminate or mitigate the risk
- Transportation
- Reevaluate/update with new information

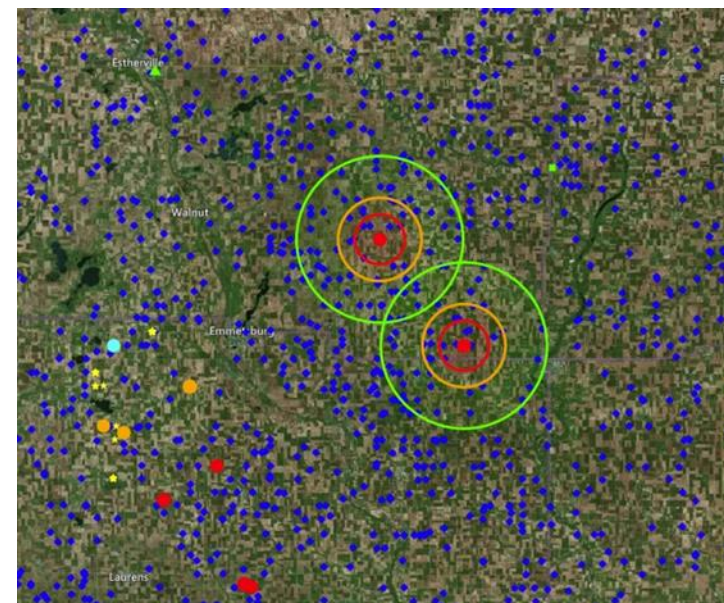


What Will Happen in an Outbreak?

- “72-hour” standstill
 - Nationwide federal order
 - No movement of live swine or germplasm
 - Identify infected farms/zones
 - Start depopulation

After 72-hour Standstill

- States will take over
- Infected premises
 - Expect restricted feed movements = permits
- Control zones
 - Potential for restricted movements, tight tracing of any movements



After 72-hour Standstill

- What can you do to ease business?
 - Dedicate trucks in a zone?
- Work with a competitor?
 - Get creative



Broad Industry Impact

- Trade:
 - All exports of porcine-based products stop
 - Broader impact – all animal-based products (16-4 health certificate)
- Supply chain disruptions
 - Pork-based products
 - Transportation challenges
- Business continuity discussions – getting back to business



Our Industry. Our Passion. Our Voice.

Label Claims Update



VOICE



REPRESENTATION



EXPERTISE



ENGAGEMENT

Adoption of One Health Policy



- Reduced use of antimicrobials
- Increased understanding of the microbiome
- Industry response--new tools

International Regulations

Country	Microbiome	Gut Function	Immunity	Contaminants	Resilience	Welfare	Physiology
Australia	Possible with Permission	Possible	Not Allowed	Possible with Permission	Possible with Permission	Possible with Permission	Not Allowed
Brazil	Possible	Not Allowed	Not Allowed	Possible	Not Allowed	Possible	Possible
Canada	Possible	Possible	Not Allowed	Possible	Possible	Not Allowed	Possible
Colombia	Not Allowed	Not Allowed	Not Allowed	Not Allowed	Not Allowed	Not Allowed	Not Allowed
Europe	Possible	Possible	Possible	Possible	Possible	Possible	Possible
Thailand	Possible	Possible	Not Allowed	Not Allowed	Not Allowed	Possible	Possible
USA	Not Allowed	Not Allowed	Not Allowed	Not Allowed	Not Allowed	Not Allowed	Not Allowed
Overall	Recognized	Partially Recognized	Not Recognized	Partially Recognized	Poorly Recognized	Partially Recognized	Recognized

Possible with Permission	Possible	Not Allowed
--------------------------	----------	-------------

Our Industry. Our Passion. Our Voice.



AFIA's Ask to CVM Sept. 2020

1. Modification of the CVM Guide 1240.3605.
2. Establishment of a policy for products which act in the digestive tract to be regulated as food.
3. Alignment with the regulation of structure/function and health claims in developed countries.

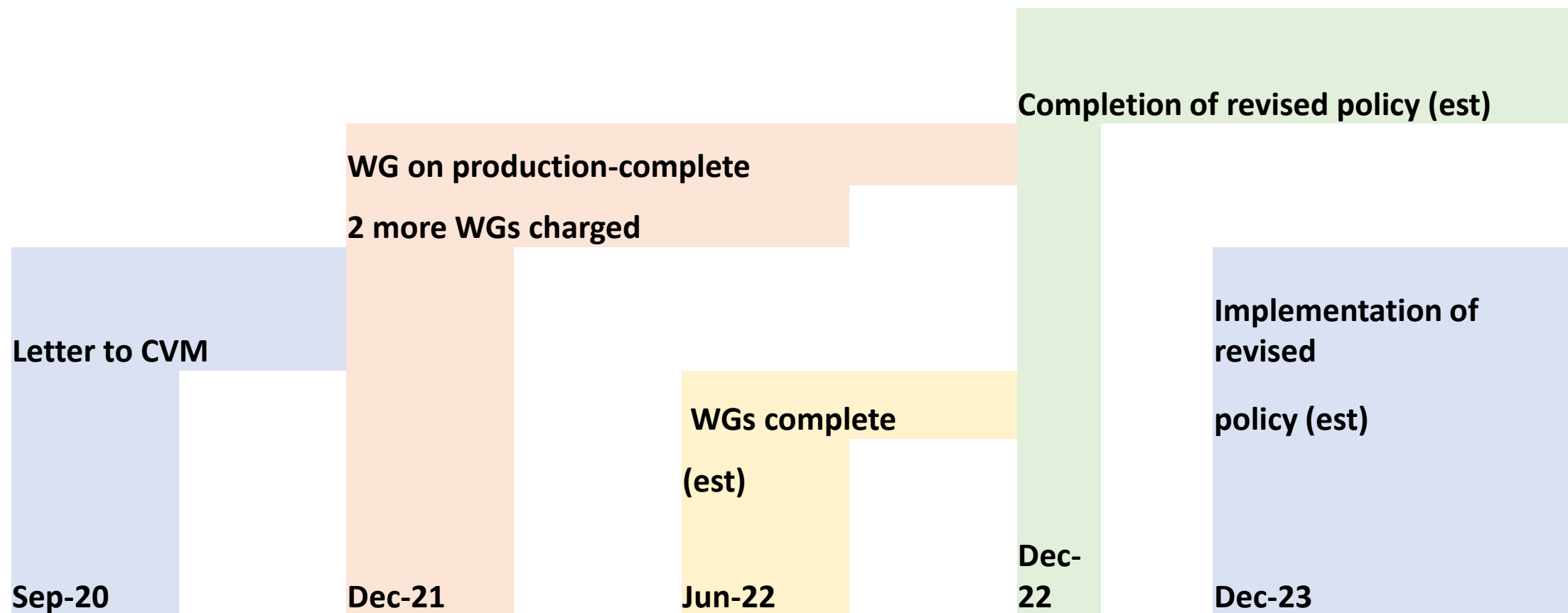


AFIA's Ask to CVM Sept. 2020

1. Animal production
2. Animal well-being (FDA: microbiome claims)
3. Human food safety
4. Environmental impact



CVM Progress Timeline





Our Industry. Our Passion. Our Voice.

Safe Feed/Safe Food Certification Programs



VOICE



REPRESENTATION



EXPERTISE



ENGAGEMENT

Safe Feed/Safe Food Certification Program

- Launched in 2004
- Voluntary, third-party certification
 - feed mills
 - feed ingredient facilities
- Promote generally accepted food safety guidelines
- Ensure continuous improvement for safe and wholesome feed for animals



The Four Certifications

- **FSC36 Safe Feed/Safe Food**

- The basic code that helps facilities become mostly compliant with the Food Safety Modernization Act's animal food rule
- Administered by SQFI

- **FSC32 Manufacture of Pet Food**

- For pet food and pet food ingredients
- Benchmarked with the Global Food Safety Initiative (GFSI), meaning it meets the internationally accepted standards for food safety within the food retail industry
- Administered by SQFI

- **FSC34 Manufacture of Animal Feeds**

- For the manufacture of animal feeds
- Benchmarked with GFSI
- Administered by SQFI

- **International Safe Feed/Safe Food**

- For North American facilities exporting internationally
- Created in partnership with FAMI-QS and is made available in cooperation with the European Feed Additives and Premixtures Association (FEFANA)
- Conforms to EU regulations for hazard analysis and critical control points (HACCP)

Program Registration Numbers – April 2022

	FSC36 – Safe Feed/Safe Food	FSC34 – Manufacture of Animal Feeds	FSC32 – Manufacture of Pet Food	International Safe Feed/Safe Food
Facilities Registered	555	107	195	43

- 900 facilities currently registered
 - 10 facilities located in Oregon
- Overall program registration has increased by 2.6% since April 2021

www.safefeedsafefood.org

Apply Now

Your manufacturing facility already excels at delivering quality feed products to the marketplace. Now – you have an opportunity to highlight your employees' dedication to the highest standards of excellence and your company's commitment to best-in-class safe manufacturing practices.

Getting Started

Click on the program below to learn how to apply.

- FSC36 Safe Feed/Safe Food
- FSC32 Manufacture of Pet Food
- FSC34 Manufacture of Animal Feeds
- International Safe Feed/Safe Food

How Long Does the Certification Process Take?

The amount of time it takes for a facility to become certified varies depending on how quickly they select a CB, prepare their facility for the audit, schedule and complete the audit, ranging anywhere from 60-150 days.

[CLICK HERE TO SEE A TYPICAL TIMELINE](#)

EVERY FACILITY THAT MANUFACTURES, PROCESSES, PACKS OR HOLDS FOOD (INCLUDING ANIMAL FOOD) IS REQUIRED TO REGISTER WITH FDA

#FEEDFACTS

Our Industry. Our Passion. Our Voice.



THANK YOU

AFIA'S

4 PROMISES



— VOICE —



— REPRESENTATION —



— EXPERTISE —



— ENGAGEMENT —

Our Industry. Our Passion. Our Voice.



afia.org

2101 Wilson Blvd. | Suite 810 | Arlington, VA 22201 | 703.524.0810