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2021 DGTC Symposium Regulatory Update

**Gary Huddleston – Director of Feed
Manufacturing and Regulatory Affairs**



VOICE



REPRESENTATION



EXPERTISE



ENGAGEMENT

AFIA Legislative Priorities

- FDA Appropriations and Label claims
- Trade
- Port/container issue



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Animal Food Label Claims

- Feed ingredients as tools to improve health, well-being, food safety and environment are being developed
- We cannot get tools to market in the U.S.
 - CVM regulates them as drugs
 - Other countries are lightyears ahead of us
 - Producers at competitive disadvantage
- Need updated interpretation of CVM policy 1240.3605



Ingredients “Ask”



- Appropriations
 - \$5 million in new funds for hiring
 - Report language urging CVM to update CVM policy- 1240.3605
- House bill
 - \$5 million and report language
- Senate bill
 - \$2 million and report language

Trade Issues Update

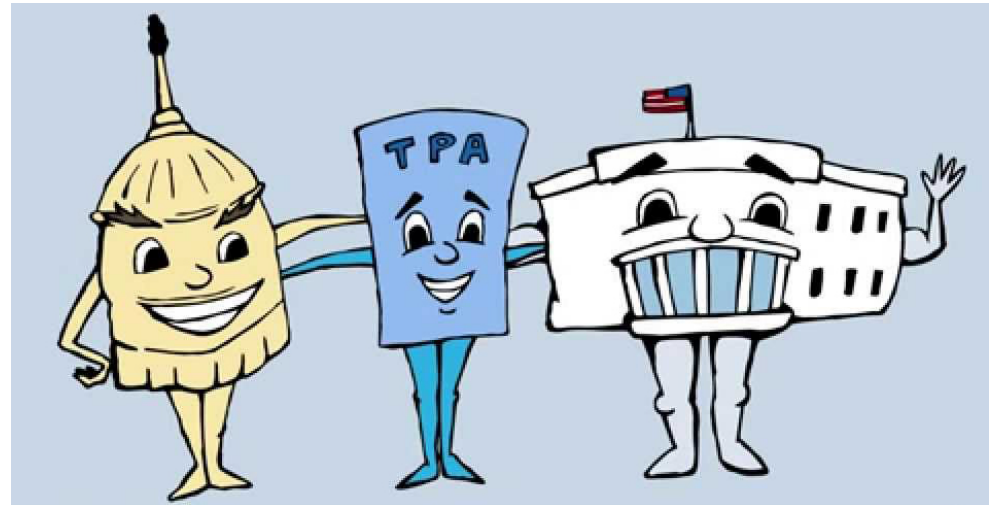


- Appointment of USTR Agriculture Ambassador
 - *Elaine Trevino, recent president of the Almond Alliance of California and former deputy secretary for the California Department of Food and Agriculture was chosen*
- Trade Promotion Authority expired in July

Trade Position and Ask

Trade Promotion Authority

Renewal of the TPA by Congress to give the president support and direction for negotiating and finalizing trade agreements.



Port/Export Container Issue

- Multiple factors leading to situation
- Increased cost of Asian-based imports
- Increased fees, inability to export
- Lack of containers to load product



Port/Container “Ask”



- Infrastructure package need
- H.R. 4996, Ocean Shipping Reform Act of 2021
 - Introduced by Reps. Garamendi (CA-3) and Dusty Johnson (SD)
 - Make several activities by ocean common carriers or marine terminal operators as prohibited acts
 - Ask for cosponsors and passage

Agencies Updates



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How are FSMA inspections going?

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Primary Types of FSMA Inspections

CGMP



Subpart B



HA/PC



Subparts C&E

- Sanitary Transportation
- FSVP

CGMP Inspections: Frequent 483 Citations

Personnel

- Failed to enforce hygienic practices

Grounds & Maintenance

- Facility housekeeping and maintenance

Holding & Distribution

- Failed to hold under proper conditions

Records Requirements

- Failed to initial, sign off on or their records were inaccurate or illegible

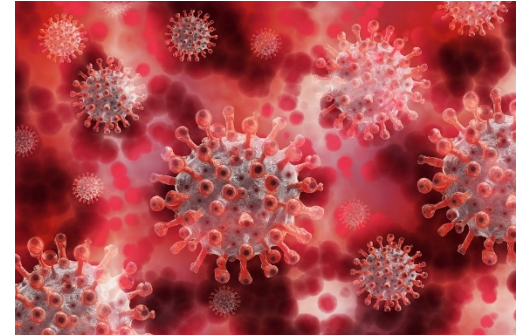
A few regarding...

- Utensils, pest control, handling rework

HA/PC Inspections: Frequent 483 Citations

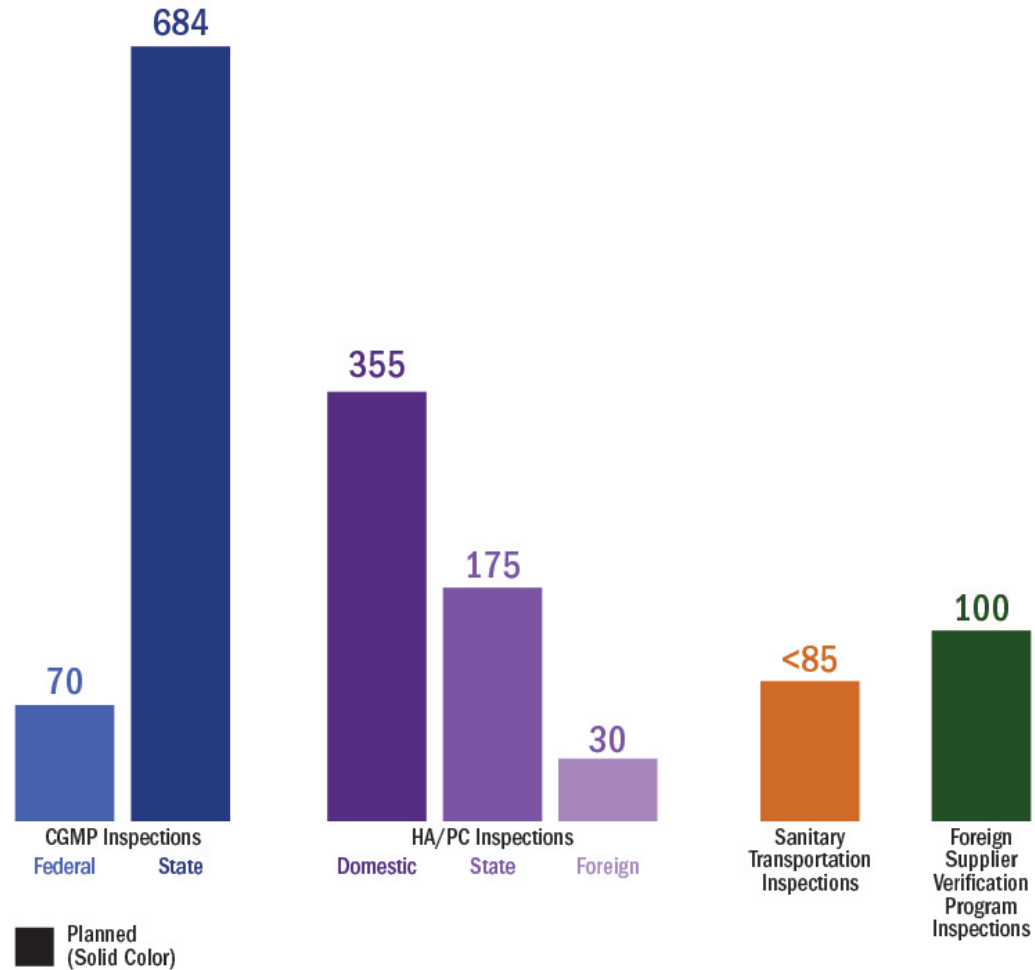
- Not identifying the need for and implementing a PC
- Failed to have a **Food Safety Plan**
- Failed to evaluate all KRF hazards
- Process PC failed to minimize or prevent the hazard
- Effectiveness of PCs not effectively verified via product testing
- Sanitation PCs not effectively verified via environmental monitoring
- Failed to conduct **reanalysis** of FSP

“2020-21 Inspections Interrupted”



- Inspection data difficult to trend due to COVID-19
- Beginning Mar 2020, inspections dramatically decreased & were “for cause” only for a while

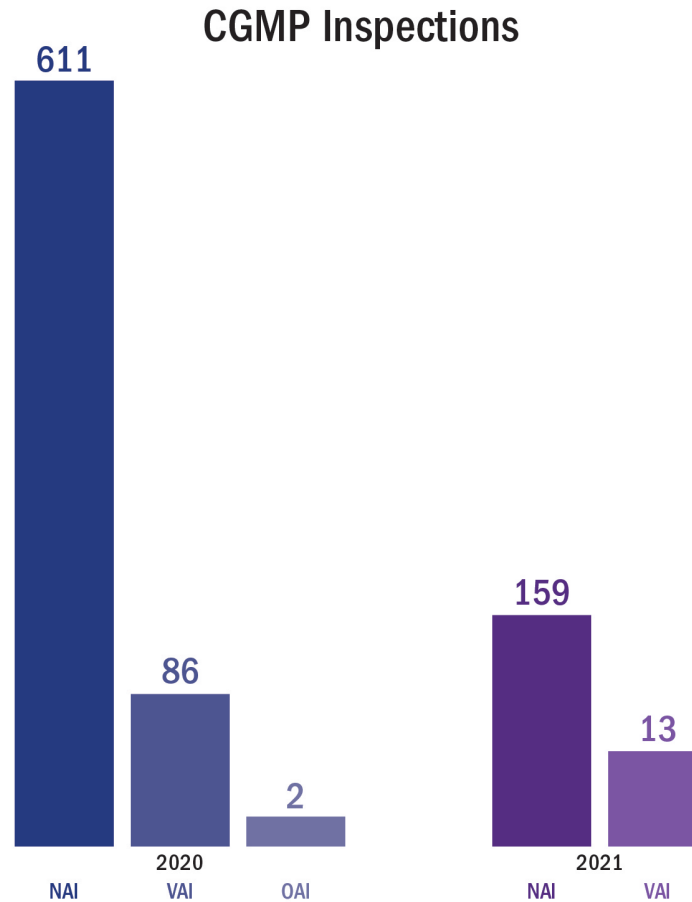
FDA FY 2021 Inspection Goals



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2020 and 2021 Inspections

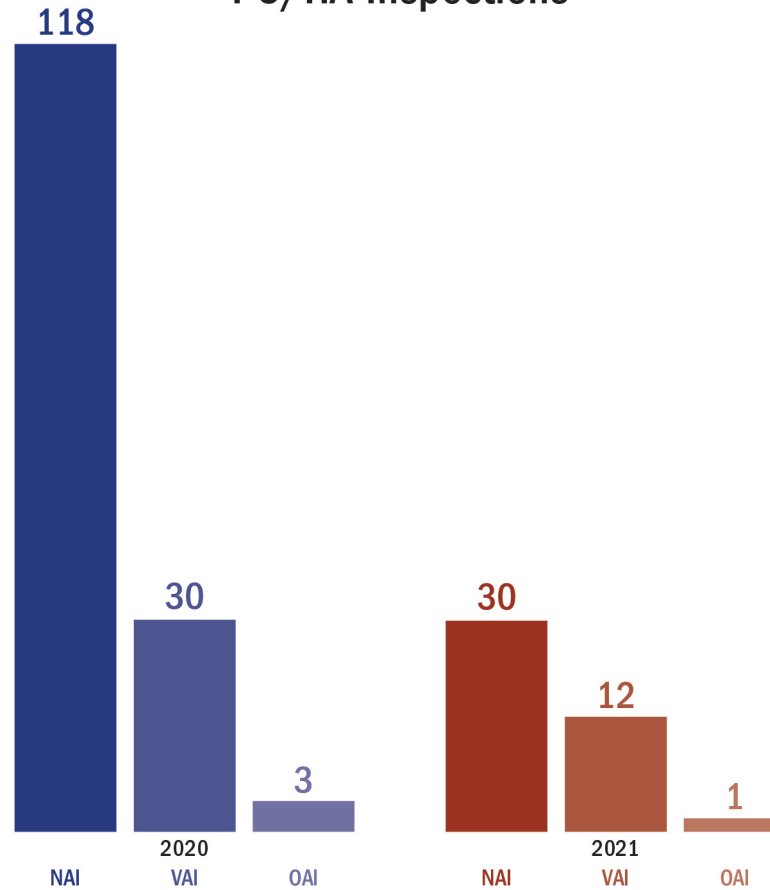


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2020 and 2021 Inspections

PC/HA Inspections

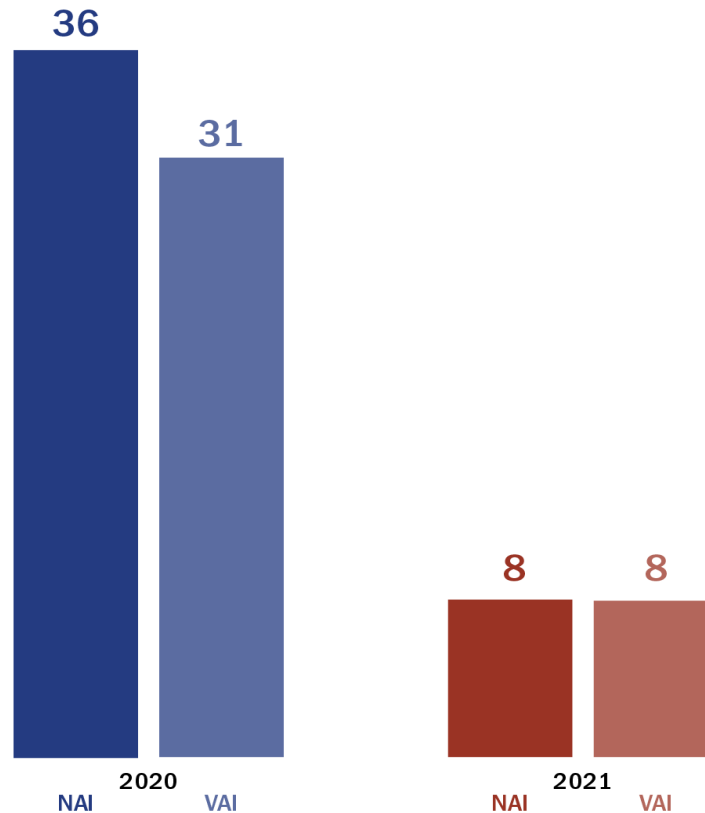


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2020 and 2021 Inspections

FSVP Inspections

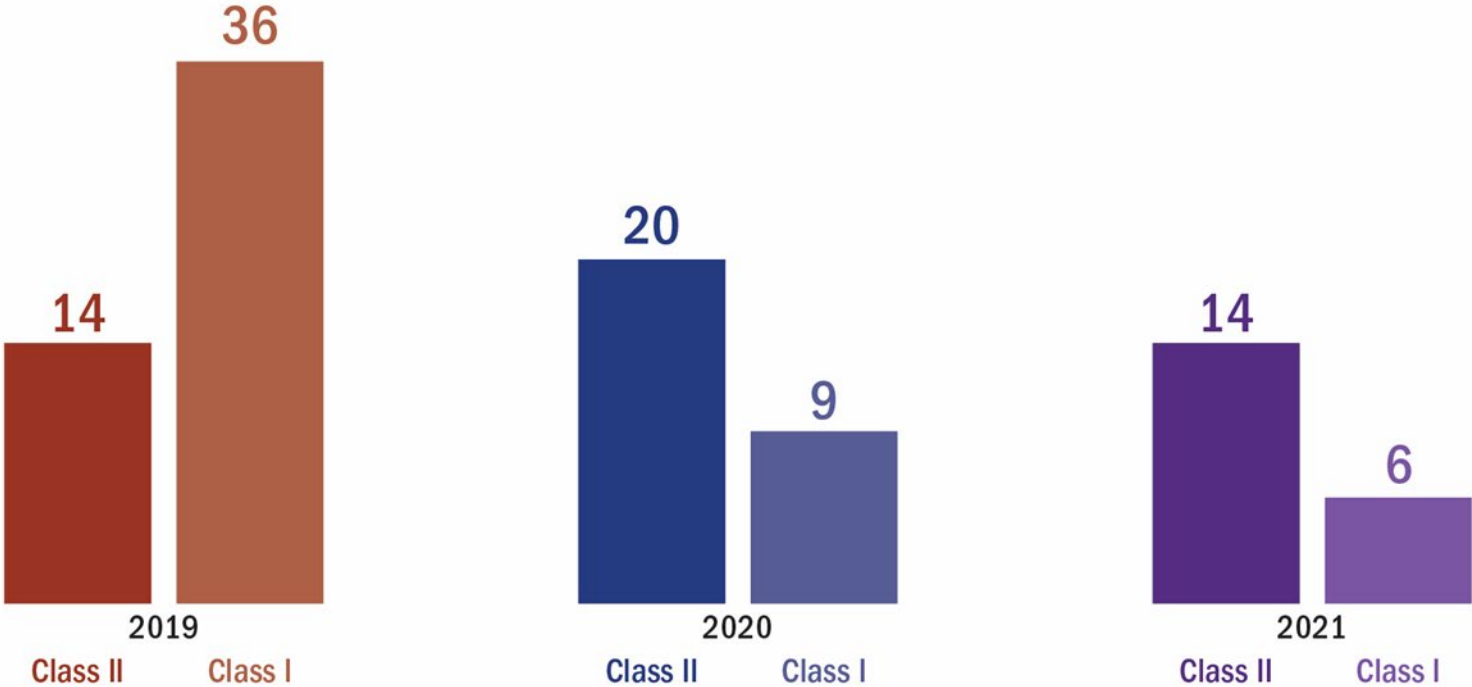


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2019 - 2021 Recalls

Recalls



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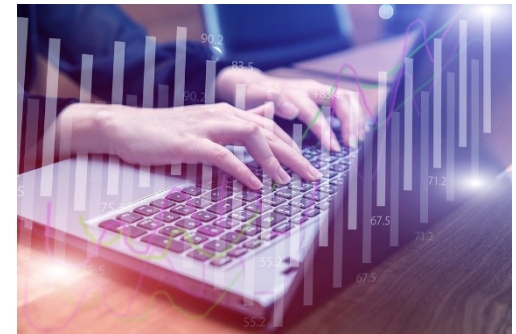
Inspections Beyond 2020?

- The new world of inspections
- What will it look like?
- Will the pandemic change the inspectional landscape permanently?
- FDA has indicated they will continue to preannounce



FDA – Remote Records

- Human food request, animal food too?
- In FSMA rulemaking - AFIA did not support
- Now = pandemic, inspections uncertain
- If proceed – AFIA “must haves”
 - Special circumstances only
 - Voluntary with no repercussions
 - No 482 = no 483
- Currently testing only with VFD Inspections
- What will this mean for other FSMA inspections?



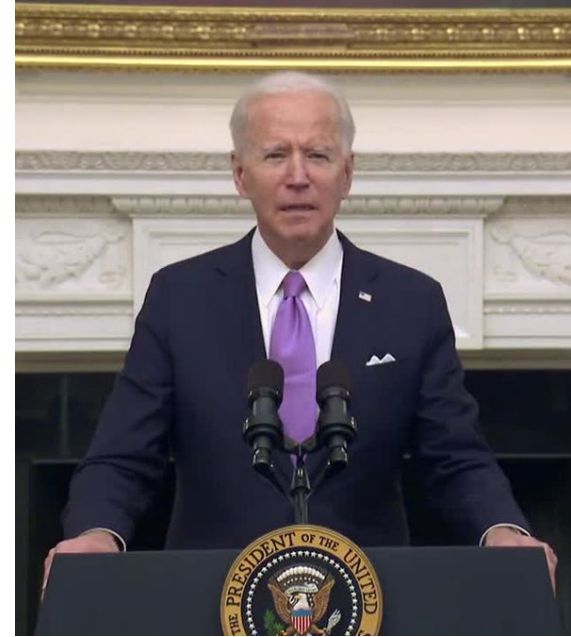
OSHA – COVID Standard



- OSHA originally proposed an ETS for all industry at the end of April (Result of Jan 20 EO)
- Concerned about potential political fallout, the administration directed them to change direction
- COVID ETS was issued for health care only in June
- Guidance for other industries was updated to reflect current CDC guidance
- Some states have an ETS in place
- President Biden announced new COVID plan Sep 9

COVID-19 Action Plan

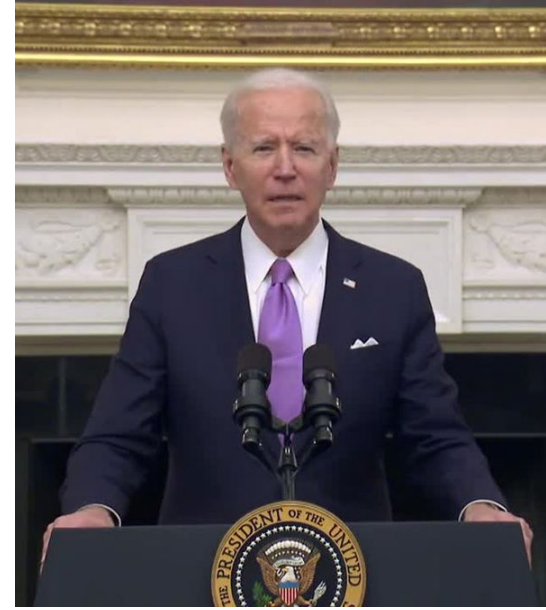
- “Vaccinate the Unvaccinated”
- Vaccine mandates for federal workers, federal contractors and healthcare workers
- Second COVID-19 ETS
 - All employers with 100 or more employees to require employees to either be fully vaccinated or get weekly testing
 - Paid time for employees to get vaccinated and recover from ill effects of the vaccine



COVID-19 Action Plan



- Who will pay for weekly testing of unvaccinated workers?
- Do employers have to provide time off for testing too?
- What documentation will be required to verify vaccination and testing status?



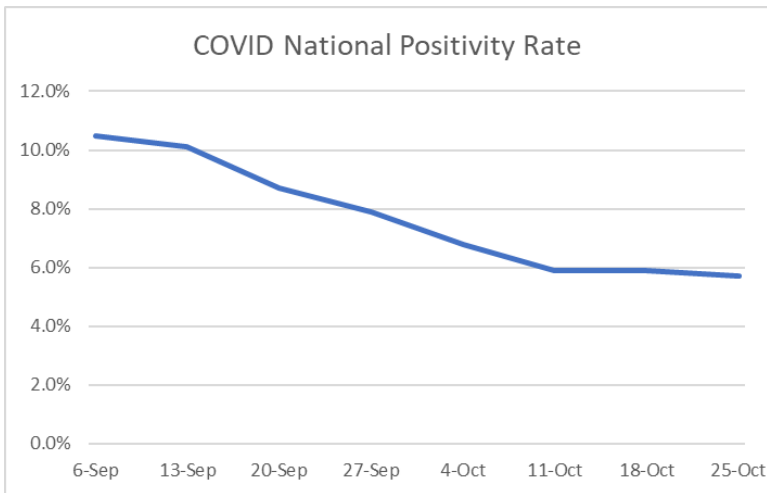
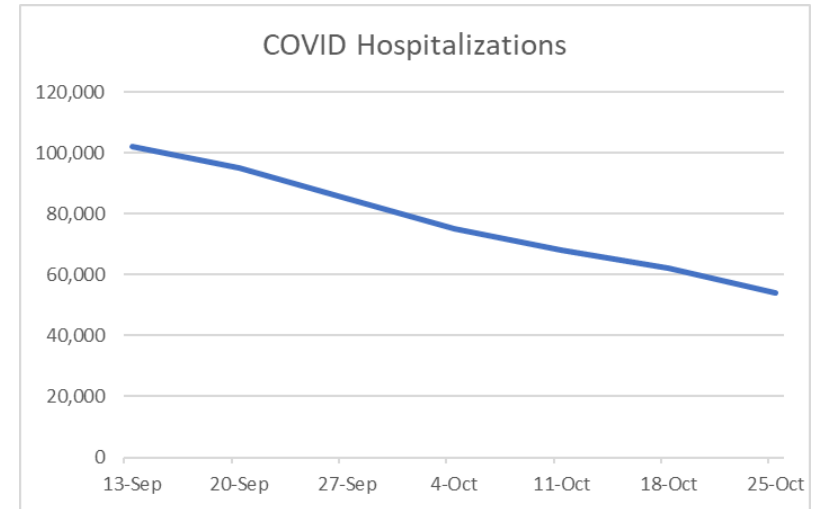
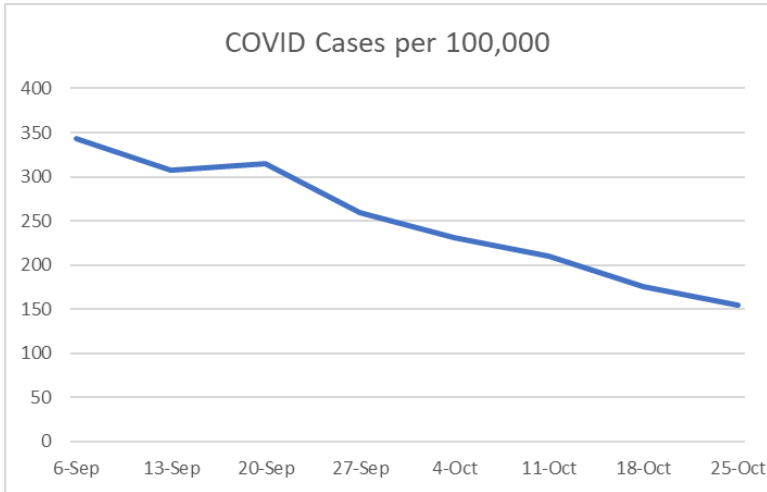
COVID-19 Action Plan



What Just Happened??

- 10/12 – OSHA delivered draft standard to OMB
- 10/13 – OIRA opened requests for stakeholder meetings
- As of 10/25 – Over 60 meetings have taken place or scheduled
- ???

COVID-19 Action Plan



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COVID-19 Action Plan



*What will this do to
an economy that is
trying to normalize?*

OSHA Watch List



- Hazard Communication Standard update
- Walking Working Surfaces Rule clarification and guidance
- Powered Industrial Trucks Rule Update
- Lockout/Tagout Rule Update
- Infectious Disease Standard
- Potential Heat Illness Prevention Standard
- Potential Emergency Response Preparedness Rule Update

EPA Watch List



- Regulation of Fluorinated Compounds (PFAS)
 - USDA and FDA looked at packaging
 - EPA formed a council to develop comprehensive approach
- WOTUS
 - EPA and Army working on new definition for WOTUS
 - Inviting stakeholders to participate in meetings
- Other items of concern AFIA is watching:
 - Prepared Feeds Manufacturing Air Toxics Rule
 - **Climate Change Regulations**

THANK YOU

AFIA'S 4 PROMISES



— VOICE —



— REPRESENTATION —



— EXPERTISE —



— ENGAGEMENT —

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