2018 Legislative Ag
Chairs Summit
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Federal Issues Plenary

Before the Plenary, Pennsylvania Senator Judy Shwank alerted attendees to a new invasive insect. The Spotted Lanternfly arrived in the US probably as eggs in packing crates imported from Asia. Thirteen counties in her state are under quarantine. It uses a sucking mouthpart to attack trees with high sugar content like sugar maple, fruit trees, hardwoods and vineyards. The tree or plant then oozes or leaks a honey dew that attracts sooty mold that damages trees and destroys grapes. The insect is a good flyer and moves on wind currents. Please contact Judy if you see this insect in your area.

Stephen Ostroff, FDA Deputy Commissioner for Foods and Veterinary Medicine
Jeffrey Sands, EPA Senior Advisor for Agriculture Policy

Stephen Ostroff covered US Food and Drug Administration aspects of the **Food Safety Modernization Act** (see *FDA presentation* handout). The foundational regulations for the act were finalized in May 2016. It is now transitioning to implementation based on thousands of public comments and in collaboration with USDA and state ag and health departments and associations. As of September 2016 a cooperative agreement with the states was funded for the implementation of produce safety rules.

Ostroff walked attendees through the FSMA compliance dates for preventive controls for human/animal foods, produce safety, sanitary transportation, foreign supplier verification, third party accreditation and intentional adulteration. The rules are staggered by farm size in terms of compliance date. Smaller entities have additional time to comply. Flexibility in implementation is built into the rules (slide 5). Education, especially with initial inspections, and assistance is emphasized to help the producer "get it right." Various groups have been funded to conduct alliance training for each of the rules.

Issues that arose around FSMA implementation (slide 9) revolved around differential treatment of "like" activities such as whether a packing house or a cotton gin is located on or off the farm, secondary activities, coloring of raw agricultural commodities and certain processing of human food by-products for animal feed (exemption for the last item is in process) FDA therefore issued enforcement discretion guidance on January 4 while it addresses these problems.

The **Produce Safety Rule** originated from recognition that the root causes of food contamination outbreaks fall into five areas (slide 10):

- agricultural water quality
- biological soil amendments
- intrusion of domesticated and wild animals into produce growing areas
- worker training and health and hygiene
- the way equipment, tools and buildings are being maintained.

Compliance dates are by farm size (slide 11):

- January 2018 for large farms
- January 2019 for small farms
- January 2020 for very small farms

There are a number of **exemptions** built into the food safety rule (slide 12). Farms with annual sales under $25,000, farms that grow for personal or on-farm consumption, farms that grow fruits and vegetables that are rarely consumed raw and farms that grow food grains are *fully* exempt. There is a *qualified* exemption for farms whose annual sales are

less than $250,000 and less than fifty percent of the produce is sold directly to consumers or restaurants/retail establishments in the same state or within 275 miles of the farm. These farms need to retain documentation that this is their sales model and label the produce as coming from that farm. FDA estimates that 47 percent of farms are covered by this exemption. However, many retailers would like for their farm providers to follow the food safety rules regardless.

Next steps for implementation of Produce Safety Rule (slide 13-15).
Biological soil amendments - FDA is conducting a risk assessment to determine how long the time period should be for the application of biological soil amendments.
Microbial standards for water quality – are probably too prescriptive. Those provisions are on hold and the compliance date has been extended to at least January 2022. The Product Safety Alliance is convening a Water Summit in Cincinnati February 27-28, 2018. Topics will include water testing methods, necessary number of water samples to obtain a baseline, frequency of testing and how calculations are done.
Product inspections - FDA does not intend to conduct any inspections until 2019.
In the interim - it is providing guidance, conducting voluntary inspections, developing farm inventories, conducting training and establishing the Cooperative Agreement Program.

Cooperative Agreement Program (slides 16-17) – Competition A relates to training and farm inventories; Competition B relates to the inspectional component. FDA will conduct CAP inspections in states that have not entered into a cooperative agreement (IL, KY, MS, ND, SD and WY) for inspections by their state ag departments. The FDA Produce Safety Network (slide 18-19) – has experts in place throughout the country.

Ostroff addressed specific questions related to **dairy issues**:
Exports of dairy-related products to China (slide 21) – FDA and China signed an MOU to provide US exporters access to the Chinese market for dairy, seafood and infant formula.
Ultra-filtered milk (slide 22) – an interim request has been granted, while regulation is being finalized, to allow the use of UF milk in standardized cheese without the need to declare on labels.
Automated milking systems (slide 23) – FDA took actions in 2017 to ensure no AMS shipper would lose Grade A status based on nonconformance to pasteurized milk standards.

Jeff Sands listed his core functions as the US Environmental Protection Agency's Senior Advisor for Agriculture Policy:

1. Institutionalize two-way communication between ag stakeholders and EPA.
2. Inform the administrator what the different ag policy offices and rural communities think of EPA ag policies. Ag is a top priority for Administrator Pruitt. Pruitt has centered the core mission of the agency around cooperative federalism.
3. Collaborate with regulated sectors to develop sensible approaches to protect the environment and human health.

Jeff addressed a number of issues under discussion at his office.

Pesticides worker protection requirements – revised certification and training rules will be out for public comment by the end of fiscal 2018.

Dicamba – manufacturers have volunteered to impose additional label requirements for over the top use including classifying it for restricted use, permitting only certified applications with special training and maintaining specific records regarding use.

Water of the US – EPA and Army are revising the scope to consider interpreting the term "navigable waters" in a manner consistent with Justice Scalia's opinion in the *Rapanos v. United States* case in 2006. This is a two-step process: 1) proposed rules and an interim step would re-codify the regulatory text that existed prior to 2015 defining "waters of the United States". 2) revision of the WOTUS definition by reviewing public comments and an additional comment period.

Question: How does EPA anticipate issuing its final rule? EPA's two-step process will use the Scalia case's definitional standard to shape the rule while relying on general counsel, Army, etc.

The renewable fuel standard – EPA has revised the volume requirements for biomass-based diesel.
Sands encouraged attendees to work with USEPA's regional agriculture advisors.

Gary Baise, Attorney, OFW Law, updated attendees on **Iowa's "ag gag" law**. (The 2012 Agricultural Production Facility Fraud law criminalizes efforts to expose violations related to animal cruelty and food safety. The law makes it a misdemeanor to obtain access to an agricultural production facility by false pretenses or to make a false statement in connection with a job application at such a facility.) The US Court of Appeals for the Ninth Circuit set a precedent by striking down the law in early January 2018 as unconstitutional and in violation of the First Amendment and equal protection and due process clauses.

Jeff Sands commented that EPA got crucified in the press. He said this was a trespass law; it was abuse of farmers, not the animals. Ag security affects all operations. He got a cease and desist order regarding further comments on the issue.

Q&A

How is the current administration **ensuring public feedback** on regulatory changes? North Dakota started the WOTUS court cases. How will ag be represented in these cases?
Jeff Sands: Administrator Pruitt has issued a directive to end EPA sue and settle (regulation through litigation).
Stephen Ostroff: If FDA moves in one direction it gets sued by consumer organizations or advocacy community. If it goes in the other direction it gets sued by a district. That can put things on hold that need to be addressed. FDA often tries to deal with those lawsuits on an individual basis.

Some states gave up preemption and let the feds take care of it. Is there any discussion about **preemption** being returned to the states?
EPA pursues cooperative federalism for state co-regulation. The spirit and functionality of what Administrator Pruitt is trying to accomplish reflects the power of states to carry out those regulations based on their expertise and local knowledge.

Missouri collects money from people who have **hazardous products** on their property. Is there a requirement for livestock operators to pay into that fund?
FDA doesn't think producers would have to report under EPCRA; only CERCLA reporting required.

FDA's approach regarding **anti-microbial resistance**. FDA worked to improve that as it relates to food animals. It issued voluntary guidance to manufacturers of medically important antibiotics to comply with removing those production uses from their labels. It had 100 percent positive response to making changes in labeling within three years. FDA is seeking feedback on a wide range of regulations that could be rolled back or re-examined. Stephen is particularly interested in finalizing regulations that have been put out in draft format and never finalized.
As of January 1, 2017 the main uses of those antibiotics would fall under the care of a veterinarian whether used therapeutically or added to feed under a Veterinary Feed Directive. Producer access to antibiotics seems to be going smoothly.

Antibiotic drug use in food animals. There are very specific statutory definitions of what a drug is. A drug is defined as something that is designed to affect the structure or function of the intended target. These genetic modifications, regardless of the mechanism of application, affect the structure and function of the animal. They fall under the FDA's definition of a drug and the drug review process. FDA has been re-examining the way it implements and uses those authorities.
FDA signed an MOU with EPA last year that provided guidance regarding new genetically engineered organisms. If the technology is used for population control, a process more analogous to pesticides, it should be regulated by EPA. However, if the application was designed to prevent or control disease, that falls under the definition of drugs and FDA's authority.