Feed Risk Consortium Meeting Report June 27, 2018

This report is not intended to be a verbatim or comprehensive recording of all the discussion. It contains paraphrased comments and interpretations from the discussion. The comments and discussion points of the group are included under each agenda item and are not be attributable to individuals.

Meeting Objective

To review current research and government policies and regulations to make recommendations to reduce the risk of feed and feed ingredients for pathogen transmission.

Attendees:

John Bare, USDA-VS; Mark Bienhoff, Kemin; Dana Cole, USDA-CEAH; Paul Davis, AFIA; Scott Dee, Pipestone Applied Research; Lisa Ferguson, USDA-NIES; Cassie Jones, KSU; Steve Larsen, NPB; Dan McManus, Purina; Jenny Murphy, FDA; Megan Niederwerder, KSU; Stacey Noe, Kemin; Russ Nugent, Tyson; Dave Pyburn, NPB; Jim Seibert, NGFA; Harry Snelson, AASV; Gordon Spronk, Pipestone Veterinary Services; Paul Sundberg, SHIC; Liz Wagstrom, NPPC; Patrick Webb, NPB. Jenna Chance and Brittany Kellen, NPB 2018 Interns.

Agenda

1. Introductions and Review of Objectives

There were no changes to the stated objective of the meeting nor additions to the agenda for discussion.

2. FDA Importation Policies and Regulations to Ensure Safe Feed and Feed Ingredients

Jenny Murphy, FDA, led a discussion about FDA's oversight of animal foods. FDA has regulatory authority over feed and feed components moving interstate.

Ingredient safety reviews:

FDA-CVM uses food additive petitions, brought from industry, Generally Recognized as Safe (GRAS) for the intended use and intended species FDA review, and ingredient definitions from the American Association of Feed Control Officials to determine the safety of feed ingredients.

Companies can do a GRAS self-conclusion without CVM review. Additional FDA resources would be needed to limit or uniformly enforce GRAS status.

Surveillance:

CVM receives surveillance "signals" from multiple sources. They look for trends in reported illnesses attributed to animal feed, consumer complaints, data from CDC, etc. There is no one set method for feed safety surveillance. There are more signals from pet food than there are from livestock feed.

For livestock feed surveillance comes from monitoring reports from a variety of sources, consumer complaints and other sources. Proactive sampling of feed or feed ingredients is rare. The surveillance results in data used to inform policy, develop communications and enhance compliance activities.

New Food Safety Regulations:

Preventive Controls for Animal Food (PCAF): This program establishes preventive control requirements for facilities required to register with the FDA. It also applies to imported human and animal food where the responsibility for control of the identified hazard is placed on the importer.

Food safety plans are facility specific. Each facility will identify reasonably foreseeable hazards and develop their plans for preventive controls.

Preventive Control program requirements include:

- A written food safety plan (FSP)
- Hazard analysis identifying reasonably foreseeable hazards to human or animal health; not all hazards can be included
- Preventive controls to significantly reduce the occurrence
- Monitoring
- Corrective actions
- Verification (including validation)
- Recall plan
- Associated records

PCAF is flexible enough to address facility-specific identified hazards and preventive actions.

Foreign Supplier Verification Programs (FSVP): The objective is to ensure safety of imported human and animal foods. The responsibility of identifying and controlling hazards is placed on the importer. The importer could control the hazards through a self-determined verification system of auditing, sampling, testing, etc.

Hazards commonly identified and applied to swine feed include Salmonella cholerasuis as the biological hazard; mycotoxins, drug carryover and nutrient deficiency or toxicity as chemical hazards; and metals and foreign materials as physical hazards.

3. USDA feed component importation policies and regulation to protect animal health

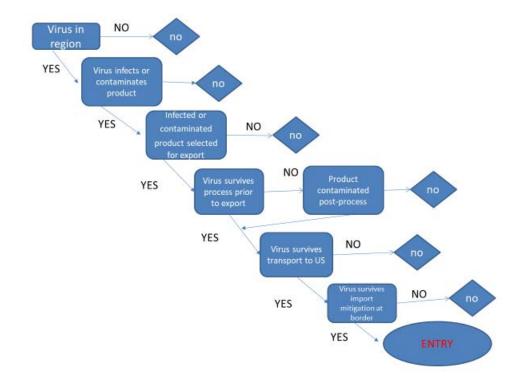
Dr. Lisa Ferguson, USDA-NIES led a discussion about USDA-APHIS authority, including APHIS import regulations. APHIS has authority for regulation of animal feed import via the Animal Health Protection Act (7 USC Ch 109) that says the Secretary has authority over "...any animal, article or means of conveyance ... if (the Secretary) determines that prohibition or restriction is necessary to prevent the introduction into or dissemination within the US of any pest or disease of livestock". Regulations are in Title 9 Code of Federal Regulations, Parts 92-98.

For regulations to apply to imported animal or non-animal products, APHIS considers source country status for diseases not present in the US (for swine, FMD, CSF, SVD and ASF), OIE guidelines and definitions for specific diseases, the WTP SPS agreements taking into account risk assessments and potential impacts on US international trade.

Non-animal origin products (feed or feed components) are not generally restricted for animal health concerns. For USDA feed safety regulation, there must be a rigorous risk assessment identifying the ability of a disease to enter the country and cause animal infection.

The example of straw import from Mexico being restricted because of the discovery of cattle fever ticks, which is an animal health concern, being found in the bales was offered as an APHIS action taken to directly protect animal health by regulating imports.

The following flow chart was discussed as an applicable decision tree for action/regulation. More research is needed to quantify and verify post-process contamination to support possible regulation.



Research has provided experimental evidence that feed ingredients may serve as vehicles for viral transport between countries. This information, along with data from studies that are currently in process should be taken seriously and used to improve risk assessment analyses, as more conclusive data do not exist. The potential economic effect of regulations based on inconclusive or speculative data supports caution when considering regulatory action. An important USDA decision point is potential impact on international trade and the limitations that might be put on US international exports by other countries. Alternatively, industry might recommend voluntary actions intended to reduce or protect itself from risk, with justification and less data than USDA needs for official action.

The goal should always be to prevent introduction of a FAD or transboundary pathogen from entering the US. Risk of FAD or transboundary entry into the country via feed may or may not be high. But we need to work to investigate, define and mitigate the risk because of its potential as a pathway.

USDA would need to consider each case's circumstances but, generally, USDA's tendency is to be as transparent as possible. If feed monitoring for FADs was done in the US and a sample was found to be positive for FMD, CSD, ASF or PRV, it could lead to reporting the finding to OIE, which could affect the US 'negative' status for these pathogens and, thus, international trade.

4. Current research program updates

Completed and current research:

- PED survival and transmission via feed
- PED infectious dose
- PED physical mitigations heat from pelleting
- PED feed mill decontamination and biosecurity
- Viral degradation in feed under transoceanic shipping conditions
- Potential mitigation products to add to feed during processing. Assessed via bioassay, using natural feeding behavior and under controlled field conditions
- Minimum/medium infectivity via natural feeding behavior, potential mitigation products and survivability in feed components – FMD on Plum Island and ASF at KSU
- SVA feed mill monitoring and sampling procedures
- Feed mill contamination risk points
- New potential feed-additive mitigation products
- Salmonella study to quantify salmonella contamination 500 feed samples is the goal; 100 anonymized facilities are currently committed to participating

Dr. Dana Cole, USDA-CEAH, updated the group on two USDA-CEAH initiatives. A literature review of feed-related risk and research is underway. USDA-CEAH is planning an expert elicitation. SMEs across government agencies have been identified – FDA, USDA-VS and CBP. Industry SMEs are yet to be identified. Expertise of the group will discuss and define

- 1. Critical characteristics of feed ingredients contributing to pathogen survival
- 2. Risk factor and critical control points in pathways
- 3. Additional information about swine pathogens in feed

The timeline will continue through 2019, with the industry SME identification and invitation beginning during the fall of 2018.

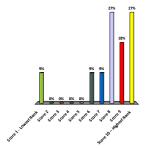
5. Research and program gaps, prioritization and collaboration – what is needed to define risk and, if necessary, mitigate it?

The group discussed and prioritized, on a scale of 1 (least important) to 10 (most important) via individual anonymous scoring, a list of agreed upon potential next steps. The Prioritization Score is the mean of the individual votes. The graphs of individual votes are included for the sense of variability of scores around the mean (1, lowest priority, is on the left of the x-axis; 10, highest priority, is on the right of the x-axis).

 Mitigation via block chain testing and traceability, Preventive Controls for Animal Food, or some other program to test and verify product safety prior to shipment from a foreign country – priority score = 8.55

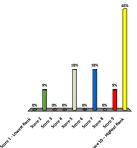
Investigate programs for verification of feed component safety prior to shipping to see if they could be used as a non-feed additive mitigation step.

2. Active monitoring of imported feed components for FADs or other transboundary pathogens at ports of entry or before shipping from source countries – prioritization score = 7.82



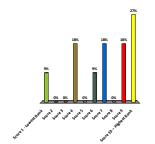
This project would inform risk assessments by testing imported feed components for FADs or other transboundary pathogens. The limitation for this project would be the country status and possible international trade effects if a feed sample already imported into the US was found to be positive for a FAD. The monitoring should be done at a foreign facility prior to shipment.

3. Minimum and median infective dose of CSF, PRV and FMD in feed during normal feeding behaviors – prioritization vote = 7.73



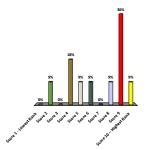
This has been done for ASF at the KSU facility. To help define risk and inform risk assessment, the same experiments would be done for CSF, PRV (at KSU) and FMD (at Plum Island). Infective dose, mitigant effectiveness and survivability will be completed.

4. Active domestic monitoring – priority score = 7.00



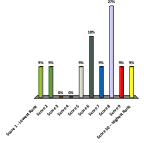
This would be a survey of feed processing mills to measure the incidence of different pathogens in these facilities.

5. Validation of environmental sampling tools – prioritization vote = 6.82



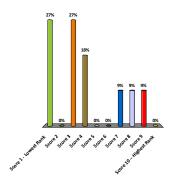
Compare dust sampling sensitivity of different sampling materials – Swiffer, sponge, swab, paint roller, etc.

6. Detectability of other viruses via environmental sampling – prioritization vote = 6.36

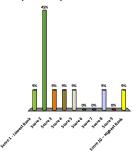


Environmental sampling has been effective for detection of PED and SVA. This experiment would demonstrate the ability to detect other viruses using environmental (dust) samples at various point in the feed processing mill.

7. Tote contamination proof of concept – prioritization vote = 4.00



Experiment to validate the use of dust samples vs. individual feed samples for detection of pathogens. Sample the dust of a tote before, during loading, after loading and after emptying to compare sensitivity of dust sampling to taking feed samples at the same times. 8. Rotavirus vs. Enterobacteriaceae use as an indicator organism during feed/dust sampling – priority score = 3.73



Enterobacteriaceae are used as an indicator organism for feed component fecal contamination. This experiment would compare rotavirus or some other enteric virus to this bacteria to investigate if a virus would be a better indicator of fecal contamination with other viruses.

Summary next step prioritization scores

- 1. Mitigation via program controls (8.55)
- 2. Active import/FAD surveillance at ports or importing countries (7.82)
- 3. MID/MED of CSF, PRV, SVA/FMD (7.73)
- 4. Active domestic surveillance (7.00)
- 5. Validation of environmental swab tools (6.82)
- 6. Detectability of other viruses via environmental monitoring (6.36)
- 7. Tote contamination proof-of-concept (4.00)
- 8. Rotavirus indicator vs. Ebac (3.73)