

Breakout Group 2A

Questions 1 and 2 -- What gaps do you agree and/or disagree with? Why?

Gap 1: *The AFSS Team is developing a method for ranking risks to animal and public health from potentially hazardous biological, chemical and physical contaminants in animal feed. The risk-ranking exercise will rank feed risks overall and also for specific feeds and/or feed ingredients (product-related risks), manufacturing processes (process-related risks), and types of facilities--feed manufacturers, transporters and on-farm mixers (facility-related risks). The AFSS Team will use this risk information to develop a risk-based approach for 1) determining which feed contaminants present the greatest risks to animal and human health and 2) deciding how such risks can be prevented or controlled.*

- Be cautious about using the word “potential” with contaminants; what is “potential”.
- Rely on science-based data to make regulations.
- Must be a consensus about the methodology used to measure and quantify risk; consider other models
- OH limited risk factors to humans? Then moved to animals? To define CCP's. Is there a dual methodology?
- CVM will be able to assess animal & human rankings separately - then develop a consensus.
- Risk ranking models should be usable to many industry participants.
- If it looks like HACCP, smells like HACCP and sounds like HACCP, is it HACCP?
- FDA is not focused on HACCP for this risk assessment model.
- Can Harvard risk assessment model be useful? Too specific?

Gap 2: *If the AFSS Team decides that limits for additional feed contaminants need to be established as action levels, tolerances, regulatory limits or guidance, analytical methods for detecting those contaminants in feed matrices will need to be developed and validated. The FDA will need official regulatory methods. Industry and government could use rapid, inexpensive and reliable test kits for monitoring of feed and feed ingredients.*

- Availability of effective, inexpensive and reliable testing methods is critical.
- Industry may need to help develop methods.
- FDA will likely not develop methods.

Gap 3: *Some of the feed hazards identified by the AFSS Team are those that may arise from deliberate contamination of feed and feed ingredients, such as bioterrorist acts. While the authority for ensuring feed safety rests principally with the FDA and the states, the USDA has the responsibility for controlling livestock diseases, even those that can be transmitted through contaminated feed, such as foot and mouth disease, classical swine fever and swine vesicular disease. USDA has traditionally accomplished this control through the regulation of garbage feeding and disease surveillance. However, the AFSS can help USDA improve methods of preventing, coordinating responses to, and investigating terrorist incidents involving the deliberate contamination of feed or feed ingredients with an exotic animal disease.*

- Historically, FDA has played a limited role in these matters.
- How does this fit into the AFSS?
- I.D. contaminating agents?
- Will determine hazard scores various agents and processes, then apply Carver score to overall system (facility).
- Can quantify risk by facility.
- Internationally, counties with various risk profiles may be quantified and categorized with respect to imports.

Question 3: What gaps have we missed?

- More emphasis on imports.
- Science based data use for international.
 - WTO problems
- Process-based program on international basis is more difficult to enforce versus product-based.
- Risk system must include entire supply chain, not any one segment.
- Will regulations be applicable to farm? End User?
Will be applicable to most risky segment
- Will criteria be segment specific to assess risk?
- Traceability
 - Not necessarily a key element to AFSS feed safety system and need to address this issue?
 - Some international sources are hurdles with respect to traceability.
- As part of program is there a response time criteria in place?
A framework in place?
- Clear direction on limits, timeframe, and consequences are needed with the AFSS.
- Can FDA link risk assessment with actions?

- How will FDA approach working with on-farm, transportation, or any portion of supply chain that FDA does not currently regulate?
- Will guidance levels be set? Toxicology methods will be used. Not part of this risk assessment.

Question 4: What solutions do you recommend to fill the gaps?

- Trade association, universities, private industry programs can be used as a resource
- Testing methodology- FDA should secure funding to develop methodology
 - Very expensive.
- FDA may be able to develop validation techniques, industry methodology.
- Search globally for technological innovations.
- Will FDA become more efficient thru AFSS implementation

Questions 5: Did we explain clearly enough how we plan to use the risk information? What was confusing about our explanation? What additional information can we provide to make it clearer?

- Show an example.
- Show what happens as you change assumptions used .
- Make safe definitions of each category defined.
 - Detailed information.
- How will risk assessment effect the current FDA new ingredient approval process?
 - Approval process will remain same.
 - Will focus on contaminants, pesticides, etc.

Questions 6: Do you think the AFSS should use a risk-based approach to determine which feed contaminants need to be reduced, eliminated or controlled in feed and feed ingredients? What other approaches should we consider?

- Any science based approach, including risk assessment should be appropriate.
- Program should keep in mind the potential media reaction.
- Informational guidance can be contributed to industry through process by FDA.
 - Not regulation?
- How will system be modified moving forward?
- Will system be designed to allow "easy" modification as environment/risks change?
 - Will continue to evaluate data.
 - Review will be a part of the system.

Question 7) Is the new definition of risk-based more understandable?

- Best available scientific information is important component of definition.
- Include “feed ingredients” in definition.
- Include “as delivered” in definition.
- “Some combination” allows definition to distribute risk appropriately across hazard and exposure.
 - May be problematic in definition.

What do you think about the four elements of the framework?

Do not appear to cover a broad enough swath of supply chain.

Transportation

Distribution

Manufacture

On-Farm

Etc.

Mention something in Element 1 context that will allow for timeliness in the approval process.

Voluntary oversight may be valuable component of regulatory element

Develop a rational, unified approach to supplements.