

Breakout Group 3B

Identified Gap in Process Controls for the Production of Feed Ingredients and Mixed Feed

1. Currently, the FDA has regulations that govern the controls used in the manufacturing, packaging, storage, and use of medicated animal feed. However, to have a comprehensive Animal Feed Safety System (AFSS), a broader regulatory approach may be required to address feed safety concerns associated with the manufacture, packaging, storage, distribution or use of non-medicated feed ingredients and mixed feed. The AFSS Team intends to consider the information gleaned from the public meetings and from responses to materials placed in the AFSS docket in its development of process control approach(es).

Question 1) Do you agree with the identified gap? Why?

- (Industry) 1) Yes, I agree with the gap - on-farm operations (non-medicated mills also)
- (FDA) 2) FDA has authority already to go on-farm FDA has authority to inspect unlicensed mills but don't routinely do these (fall under state)
- (State) 3) Some states do not have authority to go on-farm and may not want the authority.
Can go on-farm if under contract with FDA.

❖ Yes, agree with gap

Question 2) Do you disagree with the identified gap? Why?

No.

Question 3) What gap(s) have we missed?

- (Industry) 1) Transportation - how dealt with on this framework?
- Local farmer transporters
- Railroads
- 2) Need standardized form that accompanies shipments showing compliance with AFSS procedures (see Q 4).
- 3) Mixing at farm level.
- 4) Manpower to do implementation on industry side and on regulators' side.
- 5) Equal enforcement.
- 6) Cost to farmer.
- 7) Comes down to integrate or go out of business.

Question 4) What solution(s) do you recommend to fill the gap(s)?

- (Industry) 1) Need to "catch up" other groups (e.g. transporters, on-farm) before putting more regulations on feed industry.
- 2) Standardized form for compliance with AFSS - to cover farmer transporters also.

- 3) Dealing with farmers:
 - make it “appealing” for farmers to be interested in ‘products’ that are in compliance via boards, associations.
 - Certification (for buying/selling appeal, certification received due to going through training).
 - National animal ID system.
- (States) 4) Currently ID system is for disease trace-back; therefore information may not be available to do all that we may want it to do/provide.
- 5) For dealing with on-farm mixing:
 - Certification of training
- (Industry) 6) Need deadlines for training or “out of business”.
- 7) Joint meeting with producers/farmers and tell them to “bring their books”.
- (FDA) 8) Recertification after a required number of hours of training
- 9) For manpower: Don’t know.
- 10) For dealing with enforcement:
 - (Industry) *There isn’t equal enforcement now.

Question 5) How should the process control component incorporate agro terrorism concerns?

- (Industry) 1) Compliance with bio-terrorism
- 2) Impossible to check for every contaminant.
- 3) Facility security.
- 4) Know vendors.
- (States) 5) Educating parties involved/affected.
- 6) Assess the risk within your facility or process (vulnerable points) and the impact that agro-terrorism may have on those points.
- 7) Build reference list of who to call if situation occurs
- 8) Reactionary plan for “if something happens”
- 9) Training employees to look for things that are odd.

Question 6) Would it be appropriate to recommend that firms develop written Standard Operating Procedures (SOPs) for the entire feed production process? Alternatively, would it be sufficient to recommend that firms develop written SOPs for only those process steps that directly impact the safety of the feed?

- (Industry) 1) I like SOPs.
- (States) 2) Difficult to have SOPs for whole process.
- (Industry) 3) Farmers have difficulty passing the cost of keeping SOPs onto someone else.
- (States) 4) Who is going to do SOPs for farmers and mom/pop mills?

❖ Like the idea, but hard to implement at farm level.

6B. Alternatively, would it be sufficient to recommend that firms develop written SOPs for those process steps that directly impact the safety of feed?

- (Industry) 1) Difficult to separate what does not affect the safety because it all does.
2) Must be careful when writing SOPs (garbage SOP = garbage product).
3) Might consider making SOPs for known hazard. Difficult to test for everything.
- (FDA) 4) Some parts could be pulled out (exempt) from SOPs if does not affect safety, but only affects quality (e.g. size of crumble).
- (States) 5) Make SOPs generalized.

❖ Don't know - like the idea, but don't know how to implement and enforce these.

Question 7) How should the process control component incorporate feed safety-related transportation concerns for both incoming materials and the out-going product?

- 1) Refer to Q3.

Question 8) As envisioned, the Animal Feed Safety System addresses the labeling, production, distribution, and use of all feed ingredients and mixed feed regardless whether these products are produced at a commercial operation or on-farm. How should the process control component of the AFSS address the use (feeding) of feed ingredients and mixed feed on the farm? What type of on-farm controls should apply to animal feeding?

- (Industry) 1) Have meet parkers mandate (put pressure on farmers) that farmers follow procedures.
2) Comes down to economics.
- (States) 3) "Niche" market people more difficult to bring into compliance/more difficult to use enforcement.
- (Unknown) 4) Teach farmers how to read labels
- (FDA) 5) Jurisdiction over live animals may be under USDA.

8B. What type of on-farm controls should apply to animal feeding?

- (States) 1) Farmers should not have to pay for this.
2) If consumers want it, they should pay for it.
3) Farmers have obligation to produce safe food/products.
- (Industry) 4) Should the production of "safer" food be at any cost?