

Breakout Group 4A

Identified Gaps:

- 1. The agency has established priorities for inspections under the BSE inspection program based on a combination of risk factors. CVM is currently developing a risk-based inspectional approach for other feed-related inspections, which is not expected to be completed until FY 2006. The AFSS expects to rely on this approach for animal feed and feed ingredients.*
- 2. Regulatory oversight has focused principally on the commercial medicated feed industry even though there has been a major shift to more on-farm production of all types of feed. Some on-farm operations are making more feed than most commercial feed companies. Vehicles that are used to transport feed are also not receiving much inspectional scrutiny. This can be a significant cross-contamination issue. The AFSS is developing a more comprehensive regulatory approach that will cover all segments of the animal feeding industry including transporters, mixer-feeders, and livestock producers.*
- 3. Ensuring the competency and proficiency of FDA field and state inspectors, compliance officers and program personnel regarding animal feed regulations, policies and program directives is essential. The AFSS Team will be seeking input from all stakeholders on means for having the most knowledgeable feed inspection force possible. Traditional and novel approaches for providing initial and reinforcement training will be solicited.*

Question 1) Do you agree with the identified gaps?

Question 2) Have we missed important gaps?

For Gap 1 & 2

- 1) Concern using "BSE Inspection process" as guidance, i.e., are the BSE risks the same as those of overall feed/food safety? No...Therefore, develop separate risk base for feeds/foods...
- 2) Don't overlook "mobile mixers"
- 3) Size/Scale of "on-farm". Mixer needs better definition, e.g., hobby farms through integrated feed mixer.
- 4) Need more FDA/Industry Education materials, like the BSE/trucker video.
- 5) How is FDA ever going to [cover] the entire "inventory"?

For Gap 3:

- 6) Need uniformity between inspections/investigators.

Question 3) What solutions do you recommend to fill these gaps?

1. Possible solution—Industry require metal seals on all receiving
2. More & better educational materials—Broad base but need some very specific.
3. Regulatory oversight and field presence.
4. Consider 3rd party certified program and/or self-inspection program with regulatory oversight. Hopefully - reduce FDA/State inspections so that resources can be redirected.
5. Education more through "land-grant" colleges, extension agents, producer groups—for programs to all program areas—farm, hauler, etc.
----allied Industry Associations
----state groups

Question 4) The federal-state relationship is an important part of the current inspection program. How might the AFSS affect the federal-state relationship?

- 1) If AFSS becomes a federal regulation, then money necessary for funding state activities.
- 2) Individual State Regulatory Officials need to provide input to FDA.
- 3) COMMUNICATION
- 4) More uniformly comply w/ FMD 145 from district to district-specifically contract inspection reports and/or checklists.
Relationship dependent upon acceptance by ALL-industry and state officials

Question 5) Should regulatory programs focus solely on risk? How would a risk-based approach affect economic protection activities?

- 1) NO, NOT SOLELY ON RISK = IMPOSSIBLE "SALE" to state legislature as most states' laws based on economic consumer protection. (individual states' decision)
- 2) AFSS system remains "silent" on "economic consumer protection".

Question 6) If process controls are established for on-farm manufacturing and use, what would regulatory oversight for such a program look like?

- 1) With a definition of "on-farm" plan can be devised for the various types of entities (Examples):
 - Hobby farm feeder
 - "Buyers"
 - On-farm mixer
 - "sale barns"
 - Dairy
 - Mobile mixer
 - Integrated operation - poultry, hogs
 - Cattle feed lots, etc.