Feed Ban Enhancement: Implementation Questions and Answers

July 15, 2008

The 2008 Regulation

1. **Q:** What changes were made to FDA's animal feed regulations?

A: The changes to the regulations provide additional protections against bovine spongiform encephalopathy (BSE, "mad cow disease"). FDA added a new section 589.2001 to the regulations which prohibits the use of high-risk cattle material in feed for all animal species. This section builds on the 1997 BSE feed regulation at 589.2000, which remains in effect but which applies only to feed for cattle and other ruminants. Specifically, the new section 589.2001 defines the following as cattle material prohibited in animal feed (CMPAF):

- the entire carcass of BSE-positive cattle
- the brains and spinal cords from cattle 30 months of age and older
- the entire carcass of cattle not inspected and passed for human consumption, unless the cattle are less than 30 months of age or the brains and spinal cords have been effectively removed
- tallow derived from BSE-positive cattle
- tallow derived from CMPAF that contains more than 0.15% insoluble impurities
- mechanically separated beef derived from CMPAF

2. **Q:** Were any changes made to section 589.2000?

A: Yes. The definition of protein derived from mammalian tissue was changed to exclude tallow containing no more than 0.15% insoluble impurities. This means that tallow containing more than 0.15% insoluble impurities may no longer be fed to cattle and other ruminants. [*See Comment 33 and 589.2000(a)(1) page 22756*]

3. **Q:** What is the impact of the new regulation on feed manufacturers?

A: The primary impact of the 2008 rule will be on the rendering industry due to a number of specific requirements for renderers. However, feed manufacturers may be impacted by the requirement in the new rule that animal feed and feed ingredients shall not be manufactured from, processed with, or otherwise contain CMPAF. In addition, the change to section 589.2000 means that feed manufacturers will need to make sure that tallow used in ruminant feed contains not more than 0.15% insoluble impurities.

4. **Q:** Will the FDA provide a period of time after the effective date (like that given for the 1997 rule) to educate renderers about new requirements under the 2008 rule?

A: No. The 12-month implementation period is intended to provide sufficient time for the industry to become familiar with the requirements of the rule.

5. **Q:** Does the definition of CMPAF apply to material derived from livestock other than cattle?

A: No. The new rule applies only to cattle (consistent with USDA regulations, this means bos taurus, bos indicus, and bison bison) and not to other livestock species such as sheep, swine, or horses. The rule may have an indirect impact on how renderers handle other species, depending on how individual rendering companies respond to the rule.

Exclusions

6. **Q:** Will FDA list specific exclusions from the rule such as poultry fat, pork fat, recycled restaurant grease (from food offered for human consumption), and blood products to help prevent market disruptions?

A: No. This rule is clear in defining CMPAF and does not restrict the use of any other products in animal feed.

Implementation

7. **Q:** When does the new regulation go into effect?

A: The regulation becomes effective on April 27, 2009, one year after publication in the Federal Register. The 12-month implementation period allows time for the livestock, meat, rendering, and animal feed industries to adapt their practices to comply with the new regulation.

8. **Q:** What about feed manufactured before April 27, 2009 that contains CMPAF?

A: After April 27, 2009 it will not be legal to introduce into interstate commerce feed or feed ingredients containing CMPAF. Because the rule does not provide a grace period for using up feed made with CMPAF, it is expected that renderers and feed manufacturers will discontinue use of materials containing CMPAF in time to ensure that feed in distribution after the deadline is free of CMPAF.

9. **Q:** When will more detailed guidance be available for renderers, feed manufacturers and livestock producers?

A: We have started the process of developing guidance, but it will take some time to go through the formal process.

Disposal of CMPAF

10. **Q:** Can older dead stock cattle and byproducts from meat packing plants that slaughter older cattle still be used in animal feed for non-ruminants?

A: Yes, as long as the material is free of CMPAF.

11. **Q:** What is going to happen to the CMPAF that can no longer be used in animal feed?

A: A number of methods are currently available for disposing of CMPAF, including landfill, incineration, composting, alkaline hydrolysis, and burial. Another disposal option is to first render CMPAF to stabilize the material and reduce the volume, and then dispose of the rendered material by means other than use in animal feed. Whatever methods are used to dispose of CMPAF, they must comply with state and local requirements.

12. **Q:** Can ash from the incineration of CMPAF be used in feed?

A: No. The rule prohibits the use of CMPAF in animal feed and does not contain any provisions allowing for inactivation of BSE infectivity.

13. **Q:** Can CMPAF be rendered for use as fertilizer?

A: This rule does not place any restrictions on the use of CMPAF as fertilizer.

By-products from slaughter establishments

14. **Q:** How will renderers be assured that cattle offal received from slaughter facilities does not contain CMPAF?

A: Renderers must have records that demonstrate that establishments supplying cattle material to the renderer have adequate procedures in place to exclude CMPAF. These records will be considered sufficient if they include certification or other documentation from the supplier that material supplied to the renderer does not contain CMPAF, or documentation of another method acceptable to FDA, such as third-party certification. [*See Section C page 22735*]

15. **Q:** What does an acceptable certification consist of?

A: Certification is acceptable, provided it includes a description of the supplier's segregation procedures, documentation that the supplier confirms that its segregation procedures were in place prior to supplying any cattle material to the renderer, and records of the renderer's periodic review of the suppliers' certification or documentation of another method acceptable to FDA, such as a third party certification, for verifying that suppliers have effectively excluded CMPAF. [*Section C page 22735*]

16. **Q:** The rule requires periodic review of the suppliers' certification. How often is periodic?

A: The rule does not specify a frequency.

17. **Q:** A firm's written procedures are typically proprietary, so how extensive does the description of procedures need to be?

A: The rule does not specify how detailed the description must be. However, with respect to cattle materials obtained from establishments which have segregated CMPAF, such records must demonstrate that those establishments supplying cattle materials to the renderer have adequate procedures in place to effectively exclude CMPAF.

18. **Q:** How does FDA expect renderers to review the suppliers' certification or other documentation? Will certification renewal be adequate? Does FDA expect renderers to audit supplier documents and procedures – such access will most likely be denied and FDA has limited authority over such suppliers?

A: The rule does not specify the requirements of a review.

19. **Q:** Who is responsible if it is determined that CMPAF was not excluded from slaughter offal used to produce MBM for animal feed use?

A: Although all parties are expected to exercise due diligence in excluding CMPAF, the rule places the responsibility on the renderer.

20. **Q:** Will a renderer be responsible for a recall if a supplier of raw material did not remove CMPAF?

A: If it is determined that material rendered for animal feed use contains CMPAF and a recall is necessary, the renderer would be responsible for conducting the recall. However, establishing liability for the cost of the recall should not be different than for other customer/supplier business relationships.

21. **Q:** How will the new rule be enforced at small slaughtering facilities?

A: Inspections will not be conducted at any slaughter establishments, regardless of size. Inspections will be conducted at rendering facilities to verify that the renderer has determined that CMPAF is being excluded from inedible raw materials supplied by slaughter establishments.

22. **Q:** Are all specified risk materials (SRMs) required to be separated, or just the brains and spinal cords from cattle over 30 months?

A: The rule requires separation of those materials defined by the rule as CMPAF. In a slaughter facility, this means the brain and spinal cord from any animal over 30 months of age. As explained in the preamble to the 2008 rule, FDA does not believe it is necessary to prohibit from use in feed for non-ruminants any other tissues defined elsewhere (e.g. by OIE or USDA) as SRMs.

23. **Q:** Does the rule require suppliers of raw material to renderers to be trained and certified on handling their CMPAF?

A: No. FDA intends to provide outreach explaining the requirements of the rule, but does not intend to provide training to the private sector.

24. **Q:** What items specifically will not be accepted by renderers as a result of this new rule?

A: The rule does not prohibit a renderer from accepting any of the items they may currently be accepting; the rule prohibits the rendering of CMPAF for use in animal feed. Individual rendering establishments will determine what they choose to accept for further processing. A renderer may choose to collect CMPAF for disposal, as a service to slaughter establishments.

25. **Q:** Will the FDA develop a standard report to be used in recording CMPAF and/or non-CMPAF material from various sources? It would be helpful if all suppliers and all renderers use the same form for supplier certification.

A: No. FDA will not be developing a standard form, but the rule does not prevent a standard form from being used if industry chooses to develop one.

State-Inspected and Custom Slaughter Facilities

26. **Q:** Are cattle that are slaughtered in state-inspected facilities eligible for rendering for feed use?

A: Yes. 21 FR 589.2001(b)(2) defines "cattle not inspected and passed for human consumption" as cattle that did not pass antemortem inspection by the appropriate regulatory authority. In a state-inspected slaughter facility the state is the appropriate regulatory authority and animals that pass antemortem inspection may be rendered for use in animal feed provided that other requirements of the rule, such as removal of brain and spinal cord from animals over 30 months of age, are met.

27. **Q:** Can cattle offal from uninspected (custom) slaughter be rendered for feed use?

A: Yes. Cattle slaughtered under custom slaughter meet the definition of "cattle not inspected and passed for human consumption". Therefore, offal from custom slaughter operations may be rendered for feed use if the brain and spinal cord from cattle older than 30 months are excluded from the offal. Just as they would for an inspected slaughter establishment, renderers receiving material from a custom slaughter operation would need records that demonstrate that the establishment has adequate procedures in place to exclude CMPAF. **[***See comments 38 and 57***]**

Determining Age of Cattle

28. **Q:** How will renderers determine and document the age of cattle not inspected and passed for human consumption (e.g., dead stock cattle) that are collected to be rendered for feed use?

A: Renderers are required to maintain written procedures for specifying how they either remove brain and spinal cord from cattle not inspected and passed for human consumption, or how they separate such animals based on whether they are 30 months of age or older. Written procedures must be made available for FDA inspection. FDA intends to provide guidance on this issue. [*See 589.2001(c)(2)(ii) and comments 30 and 40*]

29. **Q:** What are acceptable procedures for determining the age of cattle?

A: As discussed in the preamble to this rule, FDA received a number of suggestions for ways to determine the age of cattle, including animal identification systems, dairy herd records, dentition, body weight, or feedlot origin. The rule requires only that renderers have written procedures explaining how they determine the age of cattle they process as well as records documenting their compliance with the requirement. It does not mandate the use of a specific method of determining the age of the cattle. FDA intends to provide guidance on this issue. [*See 589.2001(c)(2)(ii) and comments 30 and 40*]

30. **Q:** Can renderers accept farmer statements based on production records?

A: Yes, as long as the records meet the requirements in 589.2001(c)(3)(i) (A) or (B).

31. **Q:** What kinds of written documentation for age verification will be acceptable? Will a handwritten note, signed and dated by the owner, suffice?

A: Nothing in the rule prevents this form of documentation if it meets the requirements in 589.2001(c)(3)(i) (A) or (B).

32. **Q:** Will renderers be held liable for mistakes in statements of age?

A: Although all parties are expected to exercise due diligence in complying with the rule, the rule places the responsibility on the renderer. The renderer is expected to have procedures in place that will minimize the potential for mistakes. For example, a renderer may wish to use dentition to confirm that the producer's statement is correct. [*See comment 28, comment 40; also 589.2001(c)(2)(ii) and 589.2001(c)(3)(i)*]

33. **Q:** Will dentition be accepted as a determinant of age of cattle?

A: Nothing in the rule prevents the use of dentition as a method for determining the age of cattle. We are aware that under USDA procedures for using dentition, cattle are considered to be 30 months of age or older if at least one of the second set of permanent incisors has erupted through the gum line. [*See Comment 40*]

34. **Q:** Will renderers be required to provide training on using dentition to determine the age of cattle?

A: No.

35. **Q:** Can a renderer accept an annual statement of age (such as an affidavit) from a feedlot certifying that dead stock coming from their facility are all under 30 months of age?

A: Nothing in the rule prevents this type of documentation if it meets the requirements in 589.2001(c)(3)(i) (A) or (B).

Removing brain and spinal cord from dead stock cattle

36. **Q:** How will FDA determine that renderers are adequately removing brain and spinal cord, and will FDA have a zero tolerance for central nervous system tissue?

A: FDA has a variety of means for determining whether renderers are in compliance with the requirements in the 2008 rule, including reviewing renderers' written procedures, and observing the procedures being used while the facility is operating. With respect to adequacy of brain and spinal cord removal, the rule contains no provision allowing residual brain and spinal cord tissue in material from cattle 30 months of age or older. FDA intends to provide guidance on this issue. *[See 589.2001(c)(2)(ii), 589.2001(c)(3)(i), 589.2001(e)*]

37. **Q:** What methods are acceptable for removing brain and spinal cord from dead cattle over 30 months of age?

A: The rule does not specify what method or methods may be used. FDA intends to provide guidance on this issue. [*See Comment 18*]

38. **Q:** Can renderers use vacuum as a means of removal of brain and spinal cord from dead cattle?

A: Yes, provided the renderer has determined that the method is effective.

39. **Q:** Can renderers use direct removal (using saw to open scull and splitting carcass) from dead cattle?

A: Yes, provided the renderer has determined that the method is effective.

40. **Q:** Does the definition of CMPAF include the dorsal root ganglia?

A: No.

41. **Q:** Can the vertebral column be rendered for animal feed use if the spinal cord is removed?

A: Yes. [*See Comment 31*]

42. **Q:** Can renderers that harvest skeletal muscle and hides from dead cattle (4-D operations) continue to remove skeletal muscle from cattle carcasses to supply to mink farms and/or greyhound kennels?

A: Yes. Skeletal muscle contains no CMPAF and therefore could be removed from the carcass and used in feed for non-ruminant animals, including food for pets or mink. However, under the rule 4-D operations meet the definition of a renderer and are therefore required to ensure that CMPAF from the remainder of the carcass is properly excluded from animal feed. Such operations are also required to have written procedures in place describing the processes they use to comply with the rule. [*See Comment 30*]

43. **Q:** What does "or otherwise effectively excluded from animal feed" mean?

A: The phrase was intended to describe operations where the animal feed (e.g., skeletal muscle for pets or mink) is removed from the CMPAF (i.e. the remainder of the carcass containing the brain and spinal cord), as opposed to operations that remove the CMPAF (brain and spinal cord) so that the remaining material may be used in animal feed. "Removal of brain and spinal cord" does not accurately describe the first type of operation. [See 589.2001(c)(2)(ii) and comments 30 and 40.]

44. **Q:** Can renderers collect offal from 4-D operations and other renderers?

A: Yes. Both parties would have the same obligations to ensure that CMPAF is excluded from animal feed. [*See Comments 30 and 57*]

Dedicated equipment/transportation

45. **Q:** Can the same receiving and processing equipment be used for CMPAF and non-CMPAF materials?

A: No. The rule requires the use of either separate equipment or separate containers for CMPAF that has been separated from non-CMPAF materials. [*See 589.2001(c)(2)(iii)(A) & (B)*]

46. **Q:** On a truck, do dead cattle over 30 months of age have to be physically separated from dead cattle under 30 months of age?

A: No. The rule only requires separate equipment or containers once the CMPAF has been separated from non-CMPAF.

47. **Q:** Can CMPAF be hauled on the same truck as slaughter offal intended to be used in animal feed if it is in a separate container or compartment?

A: Yes, provided there is no cross-contamination between containers or compartments.

Tallow

Table 1

Source of Tallow	Insoluble Impurities Level	Feed Use	Caution Statement Required	Regulation
any source (non-CMPAF or CMPAF)	< or = 0.15%	allowed in all animal feeds	None	21 CFR 589.2000 and 589.2001
non-CMPAF	> 0.15%	allowed in all but ruminant feeds	"do not feed to cattle or other ruminants"	589.2000
CMPAF	> 0.15%	not allowed in animal feed	"do not feed to animals"	589.2001

48. **Q:** Where did the 0.15% insoluble impurity standard come from?

A: The 0.15% level is an internationally recognized standard for trade in tallow. The World Organization for Animal Health (OIE), in the BSE Chapter of the Terrestrial Animal Health Code, has defined protein free tallow as tallow containing no more than 0.15% insoluble impurities.

49. **Q:** Does all tallow (animal fat originating from cattle) need to contain no more than 0.15% insoluble impurities to be used as a feed ingredient?

A: Tallow containing more than 0.15% insoluble impurities may not be used in ruminant feed but may be used in feed for non-ruminants. Tallow is prohibited in all animal feed only if it contains more than 0.15% insoluble impurities and is derived from rendering CMPAF. See Table 1.

50. **Q:** Is the caution statement needed on tallow containing more than 0.15% insoluble impurities?

A: Yes. Tallow must bear the caution statement "do not feed to cattle or other ruminants if it contains more than 0.15% insoluble impurities. If it is derived from rendering CMPAF and contains more than 0.15% insoluble impurities, it must bear the caution statement "do not feed to animals". See Table 1.

51. **Q:** Does the 0.15% impurity standard apply to recycled restaurant grease?

A: FDA intends to provide guidance that will address this question.

52. **Q:** Can tallow derived from CMPAF containing more than 0.15% insoluble impurities be blended to meet the 0.15% insoluble impurities limit?

A: There is no provision in the rule to allow blending to be used to meet the 0.15% insoluble impurity limit.

53. **Q:** Will clean-out/flush-out or sequencing procedures be required if common pipelines are used to load-out fats having levels of impurities above and below 0.15%?

A: Tallow obtained from rendering CMPAF is itself CMPAF if it contains more than 0.15% insoluble impurities. Equipment or containers for such tallow must therefore be separate

from equipment or containers used for ingredients for animal feed. In addition, the change to section 589.2000 means that tallow containing more than 0.15% insoluble impurities is mammalian protein prohibited for use in ruminant feed. Section 589.2000 requires that renderers provide for measures to avoid comingling or cross-contamination by either maintaining separate equipment or facilities, or by using cleanout procedures or other means adequate to prevent carryover. Therefore, separation or other means such as cleaning, flushing, or sequencing is needed between tallow containing more than 0.15% insoluble impurities, and tallow that may be used in feed for ruminants.

54. **Q:** Is there an analytical method for determining the amount of insoluble impurities in tallow?

A: Yes. The rule specifies that insoluble impurities must be measured by the method entitled "Insoluble Impurities" (AOCS Method Ca 3a-46), American Oil Chemist's Society (AOCS), 5th Edition, 1997, or another method equivalent in accuracy, precision, and sensitivity to this method. A copy of the method may be obtained from the AOCS (http://www.aocs.org), or viewed at the FDA Center for Food Safety and Applied Nutrition's Library or at the National Archives and Records Administration. [*See 589.2001(b)(1)(vi)(B)*]

55. **Q:** What is the analytical variation (AV) for samples analyzed using the AOCS method? AAFCO does not list an acceptable analytical variation (AV) for insoluble impurities. Will acceptable variation for comparing results from different labs be developed? Will FDA verify suitability of labs, methods used, and results?

A: At this time, FDA is not aware that an AV has been established. FDA welcomes any information indicating that variation in test results is presenting difficulties in establishing that tallow meets the impurity standard. Firms using methods other than the AOCS method must have data or other information showing that the method is equivalent in accuracy, precision, and sensitivity to the AOCS method.

Import and Export of Animal Proteins

56. **Q:** Are animal proteins being imported into the US from other countries required to have CMPAF removed?

A: Yes, unless the exporting country has been designated as exempt from the requirement. The rule contains a provision allowing countries to apply for such an exemption. Any country seeking such a designation would have to provide sufficient scientific evidence to support its claimed BSE risk status. [*See 589.2001(b)(1)(vi)(C) and 589.2001(f)*]

57. **Q:** Will CMPAF removal also be required for ruminant protein meals destined for export?

A: Feed containing CMPAF intended for export is not deemed to be adulterated or misbranded if it complies with the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act.

Compliance

58. **Q:** Will FDA clarify consequences for failure in age determination or brain/spinal cord removal?

A: FDA's enforcement response for failing to comply with this rule will be consistent with enforcement responses used for non-compliance with other FDA regulations. These consequences could include opportunity to make immediate correction, warning letter, seizure, injunction and criminal penalties.

59. **Q:** Will FDA continue to use the designations NAI, VAI and OAI to categorize renderer compliance with the new rule?

A. Yes.

Recall

60. **Q:** Will a recall be required if it is determined that a renderer did not properly remove brain and spinal cord from dead cattle, or a slaughter establishment did not properly segregate CMPAF from slaughter offal, even if all parties involved made good faith efforts to comply?

A: Decisions to require recalls are made on a case-by-case basis.

61. **Q:** Would recalls concerning CMPAF be Class II or Class III?

A: Classification of a recall depends on the circumstances of an individual case.

Records

62. **Q:** How long are records required to be kept?

A: The rule requires that records be kept for one year. [*See 589.2001(e)*]

63. **Q:** Are electronic records acceptable for meeting the one year record-keeping requirement, or is it necessary to maintain the original documents?

A: Documents may be stored electronically. However, as with hard copies, electronic records must still be made available for inspection and copying, if necessary, at the time and location of the inspection.

64. **Q:** What does "track CMPAF to ensure the materials are not introduced into animal feed" mean? Are renderers responsible beyond giving up control of the material?

A: FDA intends provide guidance on this issue.

Marking

65. **Q:** What are the marking requirements in the new rule?

A: The rule requires that once CMPAF has been separated from other cattle materials, renderers mark CMPAF with an agent that can be readily detected on visual inspection. This requirement is intended to prevent cross-contamination, and as explained in the preamble to the 2008 rule, is also intended to provide a readily detectable method by which all persons in the animal feed chain can be made aware that the product is prohibited material or contains prohibited material. [*See Requirements B(1) page 22735*]

66. **Q:** If CMPAF is rendered to obtain tallow, shouldn't the finished meal be marked/dyed rather than the raw CMPAF? Marking the raw CMPAF will cause the tallow to be marked as CMPAF when, if it contains less than 0.15% insoluble impurities, it is not CMPAF.

A: FDA intends to provide guidance on this issue.