

December 20, 2005

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852.

***Docket No. 2002N-0273, Substances Prohibited From Use in Animal Food or Feed***

The California Department of Food and Agriculture (CDFA) is not opposed to further strengthening safeguards designed to help prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. However, any further regulations must also take into consideration the benefit versus the cost of such regulations. CDFA has concerns that implementation of the rule as proposed, could inadvertently lead to an animal carcass disposal crisis in California, and cause negative impacts to animal health, public health and environmental health. CDFA has identified concerns regarding implementation of the proposed rule. Prior to implementation of such a rule, CDFA requests federal support to explore alternative means of disposal and adequate time for the rendering industry to make the necessary changes in their facilities and operations in order to comply.

**DISPOSAL ISSUES**

**1) Disposal Alternatives Proposed by FDA and Their Feasibility in California**

As indicated within Page 58590, FDA proposes the following disposal alternatives: landfilling of CMPAF without rendering, rendering for disposal, disposal through alkaline hydrolysis digesters, incineration, and composting.

- a. *Landfill disposal:* Currently, California statute prohibits this as an option and it prohibits the transportation to sites other than licensed rendering, licensed collection sites, nearest crematorium and animal disease diagnostic laboratories acceptable to the CDFA. (California Code: Div. 9 Part 3. Chapter 5. Article 8. Section 19348).
- b. *Rendering for disposal:* This is a feasible option but increases disposal costs, in part through the need of dedicated equipment at the rendering plant, which can only be recovered by increased pick-up fees to cattle producers. The California rendering industry has shared that the pick-up fees will increase 50% or more depending on class. Past increases in fees have already driven some producers to consider disposal methods, such as burial that even when legal could potentially be detrimental to environmental and public health. Alternate disposal options available to producers do not remove animal and human pathogens as effectively as rendering.

- c. *Disposal through alkaline hydrolysis digesters*: This alternative is not feasible considering the volume of demand and would require building cost-prohibited facilities.
- d. *Incineration*: This would require enhancing current capacities or establishing new facilities and would be extremely expensive because of California's strict air pollution measures. In some areas of the State it may even be prohibited.
- e. *Composting*: Currently, California regulations prohibiting the composting of mammalian tissue (Title 14 Chapter 3.1, Article 1, Section 17855.2. Prohibitions) make this alternative not feasible for California.
- f. *Burial (mentioned elsewhere in the document)*: Many dairy producers in this State have limited land available because of their production practices. Also, most dairy "sheds" in the State are experiencing urban encroachment leading to increasing restrictions on land use practices. Southern California dairies are the most impacted regarding acreage and encroachment.
- g. Given that the use of landfills and composting of mammalian protein are currently illegal in this State and that the infrastructure does not exist for large scale incineration or alkaline hydrolysis digestion, the alternatives to rendering of CMPAF are very limited and could result in unwise and/or illegal burial or dumping that could be detrimental to public, animal and environmental health if rendering becomes unavailable due to the impact of this rule.

**2) Volume Raw Product to be Diverted from Animal Feed in California and Current Role of Rendering Industry with the State**

- a. Contrary to the national demographics depicted within the FDA proposal (~21%), dairy comprises approximately 71% of the adult cow population in California.
- b. Dairies are more concentrated within certain regions of the State than are beef producers. The rendering industry is situated strategically to service the large California dairy industry.
- c. Historically, dairy "sheds" in the State were established so they could more easily serve populated areas, and population growth naturally expands towards the dairy "sheds". Today several dairy "sheds" within the State - Riverside/San Bernardino counties being the most extreme - are on the edge of large urban areas. If rendering were not available they would not have a viable legal option for disposal.
- d. Several California dairy experts agree that the annual death loss in adult cows alone, *including* non-ambulatory cattle, on California dairies is approximately 6%, or more than 104,000 cows per year.
- e. Based on communications with and statistics provided by the State's rendering industry, they are currently processing the vast majority of the dairy "deads". For cattle over 30 months of age, the State's rendering industry estimates processing over 131 million pounds of material. This equals or even exceeds the estimated number of head noted in part d. The

extent that dairy cattle over 30 months of age are being rendered in California, illustrates that the rendering industry plays a much more important role in the safe disposal of cattle carcasses in California than assumed by the FDA comments in the proposed rule.

The rendering industry has indicated to CDFA that removing the brain and spinal cord from all “cattle not inspected and passed” would not be practical; they would actually have to remove the entire head and spinal column, greatly increasing the volume of byproduct to be diverted from the feed chain. California estimates 550,000 cattle of all ages currently enter the rendering system. The proposed rule estimates that only 1.3 pounds would need to be diverted from each animal by removing the brain and spinal cord – or a total of approximately 700,000 pounds. However, when the reality of removing the entire head and spinal column is included and using the estimated weight of SRMs provided by the proposed rule (an average of 36 pounds for the classes of carcasses currently rendered in California) a conservative estimate is 20 million pounds of byproduct to be diverted.

Additionally, only about 37% of the cattle receive by the California rendering industry is suitable for removing the head and spinal column – the remaining 63% are too decomposed to assure safe removal. This would result in diverting approximately 350,000 entire carcasses from the feed chain in California. The total byproduct from removing the head and spinal column from approximately 200,000 carcasses, and diverting 350,000 entire carcasses, would be about 132 million pounds. This is obviously a much greater burden on California than the estimated 700,000 pounds in the proposed rule.

If California rendering did not accept all “cattle not inspected and passed”, over 200 million pounds of byproduct would need to be safely diverted from the feed chain.

### **3) Time Needed for Implementation of the Proposed Rule**

- a. Regarding disposal options of land-filling or composting of CMPAF or carcasses, statute and regulatory changes would be required and safety data for evaluating alternative disposal methods would be needed. This process could take many months to years to complete. Concerns go beyond BSE. Safety, with respect to other zoonotic pathogens (i.e., *Clostridium botulinum*, and *Bacillus anthracis*) must also be evaluated. Additional hurdles that would have to be overcome include:
  - i) Approximately one-half of the landfills in the State are privately operated and may choose not to accept cattle materials because of the additional handling necessary and due to concerns over public perception.

- ii) Most landfills are not designed to handle these materials easily.
  - iii) Some landfills might not be able to process the leachate from cattle materials without modification.
  - iv) Costs for transportation, handling, and landfill costs are likely to be much higher than estimated in the proposed rule.
  - v) Commercial composting operations, whose market is fragile, would also be reluctant to use carcasses or other animal materials because it might further restrict their markets.
- b. Regarding rendering for disposal, plants would need to establish dedicated equipment for processing. Communications with California's rendering industry suggest this could take more than one year to complete and extensive capital to accomplish. Increased costs could only be recovered through pick-up fees and past experience illustrates that fewer producers would likely use rendering as an option.
  - c. Regarding the options of alkaline hydrolysis or incineration, establishing the infrastructure would take months, would need substantial capital, require extensive review and approval by environmental regulators, and would not be practical considering the volume requiring disposal.
  - d. Within the docket, FDA acknowledges the IRT report's statement that the U.S. does not currently have the infrastructure to handle the disposal needs generated by an SRM ban and that staged implementation would be wise (page 58575). CDFA believes that this is true even for the current proposal and must be considered.
  - e. If the implementation is not staged, the appropriate mechanisms, such as the alternative disposal methods suggested by FDA will not be available in California and renderers might be driven out of business, leaving no legal or safe alternative for CMPAF and carcass disposal. This might be an even greater concern in this State than others because of the close proximity urban population to concentrated dairy production areas.

#### 4) **Effects of Increased Costs**

- a. Increased costs to the rendering industry may cause some companies to simply shut down and go out of business. Those that choose to operate under the new requirements would need to recuperate costs by increasing pick-up fees. Information provided by the California rendering industry suggests that if they were to accept carcasses and remove the head and spinal column that pick-up fees would increase from 50% to 80% of today's charges depending on the class of cattle.
- b. Increased pick-up charges will encourage producers to find alternatives to rendering which currently is serving as an important tool for BSE surveillance. In addition, USDA is including the rendering industry in developing future surveillance programs for animal diseases. These efforts would also be negatively impacted if the rendering industry is not able to receive and process these animals.
- c. Further loss of the rendering industry would also negatively impact the developing national animal identification system. Renderers will provide

a key component by collecting ID from animals that die on farm, thus providing final destination and removing them from the system.

- d. Previous increases in pick-up charges have resulted in some illegal transportation and dumping of carcasses that have caused environmental and public health dilemmas.
- e. Subsidizing costs or providing low interest loans could assist in lessening some of the negative impact.

**5) Alternative Disposal Routes That Should Be Considered and Supported By Federal Policies**

- a. Considering the need for investment in infrastructure to address this challenge, we strongly encourage FDA to collaborate with U.S. EPA and USDA to explore options and incentives to utilize animal carcasses and other associated byproducts as raw materials for the production of biofuels.

**FEED INSPECTION ISSUES**

- 1) The issue of regulatory responsibilities of FDA in slaughterhouses and packing plants regarding verification of the removal of CMPAF from raw ingredients used by the renderers to manufacture animal feed products has not been clearly defined in the proposed rule.
- 2) Requirements of slaughter plants to maintain records, verifying that raw ingredients sent to renderers for processing into animal feed is free of CMPAF should be considered.
- 3) Tallow derived from carcasses inspected for human consumption with SRM removed, could be fed without the 0.15% insoluble impurities restriction.
- 4) Feed manufacturing and transportation sectors not handling prohibited material should not be required to use dedicated equipment. However, equipment for processing or transporting prohibited material should be specifically designated for such purposes only.

**CONCLUDING REMARKS**

CDFA is not opposed to further strengthening safeguards designed to help prevent the spread of BSE in U.S. cattle. However, we believe that FDA has not adequately evaluated the potential animal disposal crisis that is likely to follow in certain regions of the U.S., including California. If this rule is implemented, it must be done slowly and deliberately to allow adequate infrastructure and alternative methods of carcass disposal to be developed. Further we encourage that FDA collaborate with other government agencies to ensure that animal, public and environmental safety are addressed regarding selection of alternative disposal methods before the proposed rule is finalized. A joint risk assessment conducted by USDA, FDA and EPA to

evaluate animal, public and environmental health impacts vs. the benefits of the proposed rule is recommended before action is taken. Ideally this would be the time for all federal agencies to develop options and incentives to utilize animal carcasses and other associated byproducts as raw materials for the production of biofuels.