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August 13, 2004

Docket No. 2004N-0264
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir/Madam:

Re: Docket No. 2004N-0264 (RIN 0910-AF46); Federal Measures to Mitigate BSE Risks: Considerations for Further Action.

Darling International Inc., as one of the largest independent rendering companies and processors of animal mortalities in the United States, submits the following comments in response to the above Notice, issued jointly by the Center for Veterinary Medicine (CVM) of the Food and Drug Administration (FDA) (Docket No. 2004N-0264) and the Animal and Plant Health Inspection Service (APHIS) (Docket No. 04-047-1) and Food Safety Inspection Service (FSIS) (Docket No. 04-021ANPR)) of the United States Department of Agriculture (USDA).

The questions asked by the FDA indicate a change in that agency's philosophy towards mitigating the risk of bovine spongiform encephalopathy (BSE). In the past, the FDA has attempted to manage BSE risk by controlling the use of animal-derived feed ingredients. The current ANPR suggests the agency plans to manage this risk in the future by removing tissues most likely to contain the BSE infectious agent from the animal feed stream, which is consistent with recommendations made by the International Review Team in their February 2004 report to the Secretary of Agriculture.

Since a case of BSE was confirmed in the United States on December 23, 2003, the FDA has expressed increased concern over the potential exposure of cattle to restricted use proteins, such as meat and bone meal (MBM) derived from ruminant animals, through cross-contamination and on-farm mixing/feeding errors. Removal of specified risk materials (SRM), non-ambulatory cattle and dead cattle from feed will certainly reduce the risk of amplifying the disease via accidental exposure, provided such additional prohibitions can be enforced.

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The Harvard-Tuskegee Study¹ emphasized the importance of the feed ban, instituted in 1997 by the FDA (21 C. F. R § 589.2000; “Feed Rule”), as one of the most important measures for reducing the potential spread of BSE in the United States. They further suggested that removing animals that die on the farm and SRM from animal feed will reduce the potential for new BSE cases by 82 % and 88%, respectively. **However, Darling International Inc. believes that in order to obtain the risk reductions predicted in the Harvard-Tuskegee Study, regulations pertaining to the collection, handling, processing and disposal of raw SRM and dead cattle must be developed and enforced. One such model regulation is attached to these comments as Appendix A.** Failure to develop such regulations will remove all controls over the ultimate disposal of these materials and exacerbate the improper and illegal disposal of raw animal mortalities and byproducts. In effect, efforts to avoid the risk of BSE in the U.S. will inadvertently weaken the rendering industry and conventional pathogenic agents that have been controlled by rendering in the past will create a greater biosecurity threat to both animals and humans.

The International Review Team acknowledged that the United States does not possess an infrastructure for the safe handling and disposal of SRM and cattle mortalities. The rendering industry can provide such an infrastructure, provided the disposal of these materials are regulated and such regulations are enforced.

It is not logical to prohibit the rendering of SRM, non-ambulatory cattle and dead cattle to make ingredients for animal feed and pet food without a comprehensive plan that insures that these materials will be safely and responsibly disposed of. Failure to develop and implement such a plan will threaten human and animal health and damage the environment.

Key Issues Open for Comment:

1. USDA asks: Would there be value in establishing a specialized advisory committee or standing subcommittee on BSE?

Most of the risk mitigation steps discussed in this ANPR affect the rendering industry, which is not regulated by a single federal or state agency. As a result, regulations promulgated by a single agency may have unintended consequences and result in disposal issues, such as: contamination of soil, water or feedstuffs with the BSE agent; endangerment of animal and human health; and/ or damage to the environment. Establishment of a specialized advisory committee representing all industries impacted by BSE regulations may prevent such problems and further strengthen the firewalls against BSE, while maintaining existing controls over the proliferation of conventional pathogenic organisms.

¹ Cohen et al., 2001 (Revised 2003). Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States. Harvard Center for Risk Analysis, Harvard School of Public Health and Center for Computational Epidemiology, Tuskegee University.

2. **FSIS and FDA ask:** *What data or scientific information is available to evaluate the IRT recommendation described above, including that aspect of the recommendation concerning what portion of the intestine should be removed to prevent potentially infective material from entering the human food and animal feed chains?*

We are not aware of any new scientific information. The distal ileum and associated tissues are the SRM. However, there is a general lack of agreement as to how much of the ileum to remove in order to insure that the potentially infectious portion does not enter the food or feed chains. Even experts do not always agree on how to distinguish between the ileum and jejunum upon gross examination. Therefore, it is logical to require that the entire small intestine be removed in order to insure that the distal ileum is adequately removed.

Darling International Inc. does not disagree with comments pertaining to this question made by the Center for Food Safety and Applied Nutrition in their recent Interim Final Rule:

“(1) It is difficult to distinguish one end of the small intestine from the other once the organ has been removed from the animal, (2) there is no international agreement on how much of the small intestine should be removed to ensure that the distal ileum is separated from the upper part of the intestine, and (3) there is no way for a manufacturer or processor to document that the distal ileum was adequately removed since there is no international consensus on the issue.”²

3. **FDA asks:** *What information, especially scientific data, is available to support or refute the assertion that removing SRMs from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or of feeding error on the farm?*

Total compliance to the FDA Feed Rule will prevent the spread of BSE, because cattle will not be exposed to any ruminant tissues, including the SRM. However, to address the specific question asked by the FDA, removing SRM tissues from animal feed will certainly reduce the risk of spreading the disease through cross-contamination or on-farm mixing error in two ways: 1) the intervention step will be moved from the feed mill or on-farm mixer/feeder to slaughter and/or rendering facilities, which are fewer in number making them easier to regulate, and 2) the potentially infectious tissues will not be present in the feed chain. In fact, such a prohibition would technically make ruminant derived MBM safe to feed to ruminant animals.

What information is available on the occurrence of on-farm feeding errors or cross-contamination of ruminant feed with prohibited material?

To our knowledge, such information is not readily available and is dependent on the accuracy and depth of records kept on farms. Many livestock feeders keep only those records important for measuring production and/or economic performance and efficiency. It is unlikely that the FDA will be able to determine the frequency of on-farm mixing errors without intense inspections of such feeding operations.

² Interim Final Rule: Use of Materials Derived from Cattle in Human Food and Cosmetics docket No. 2004N-0081. Federal Register. Vol. 69, No. 134, page 42259.

4. ***FDA asks: If SRMs are prohibited from animal feed, should the list of SRMs be the same list as for human food?***

Yes. Consumers do not understand BSE related issues very well and will likely have difficulty with the concept that certain tissues are SRM for food, but safe to feed to livestock, poultry and pets. Therefore, adopting a different or less comprehensive list for feed will be confusing to the consumer and undermine their confidence in food safety and, specifically, beef produced in the United States. Managing two lists of SRM will also complicate enforcement and verification efforts.

What information is available to support having two different lists?

The SRM were defined by FSIS in their Interim Final Rule³ and are already being removed at slaughter. Because SRM vary in their potential BSE infectivity, with the brain and spinal cord accounting for more than 89%, it may be possible to justify the removal of some, but not all, SRM from animal feed, using cost-benefit analyses. However, if the term “SRM-Free” has a dual meaning, the resulting uncertainty in the domestic and export markets will invalidate any prior economic analyses. We expect these markets to eventually recognize only the complete FSIS list of SRM and require removal of all such tissues from MBM. Such a market imposed ban will reduce the market value and demand for any MBM derived from animal byproducts containing some of the SRM prohibited by the FSIS, but not prohibited by the FDA.

5. ***FDA asks: What methods are available for verifying that a feed or feed ingredient does not contain SRMs?***

We are not aware that methods exist to test feed/feed ingredients for all of the SRM tissues listed by FSIS. Enzyme immunoassays are used as an enforcement tool by the FSIS to test raw meat products for central nervous tissues (CNS), with a detection limit of $\leq 0.1\%$. However, such assays may not be suitable to detect small intestine or other non-CNS SRM. To our knowledge, the enzyme immunoassay used by FSIS has only been validated with uncooked material and may not reliably detect CNS in material after it has been heat processed, as in a rendering facility.

The most practical and expeditious method for verifying that a feed or feed ingredient does not contain SRM is to regulate the disposal of such prohibited materials in licensed disposal facilities. We have drafted a rule that would provide for the development of such an infrastructure (Appendix A), initially derived from existing rendering facilities that could be dedicated as disposal facilities.

³ January 12, 2004. Federal Register volume 69, No. 7 pp 1862-1874.

6. **FDA asks:** *IF SRMs are prohibited from animal feed, what requirements (labeling, marking, denaturing) should be implemented to prevent cross-contamination between SRM-free rendered material and material rendered from SRMs?*

Labeling, marking and/or denaturing SRM alone will not be adequate to insure that these materials do not enter the feed chain. Therefore, Darling International Inc. encourages the FDA to maintain control of SRM and require that these prohibited materials are disposed of only in licensed disposal facilities as described in Appendix A. All shipping containers, cans, receptacles, trailers and vessels used to transport or store raw SRM and finished prohibited products, such as MBM derived from SRM, should be clearly labeled with appropriate language such as “NOT FOR HUMAN CONSUMPTION” and “NOT FOR ANIMAL CONSUMPTION”.

Raw SRM and other prohibited materials may be denatured according to procedures set forth by the USDA⁴. Other methods of marking or identifying these materials for enforcement purposes may also be suitable, provided they do not prevent their use as a biofuel or in products that might be developed by the industry and then approved by the FDA at some future date.

7. **FDA asks:** *What would be the economic and environmental impacts of prohibiting SRMs from use in all animal feed?*

The present ANPR does not address what is to happen to SRM if they are not rendered into MBM for animal feed. Therefore, we can only assume that the proper disposal of these materials has not been addressed by USDA and/or FDA. We agree with the FDA’s estimate that 1,423,044,000 pounds of SRM are produced each year in United States⁵. Failure to use the rendering industry for the disposal of these materials will bypass the infrastructure developed to handle animal byproducts and mortalities, resulting in sanitation and environmental challenges in the future⁶.

Without the rendering industry, it will be necessary to discard or dispose of SRM and any other animal byproducts/mortalities that are prohibited from feed, in community landfills, compost piles, burial sites, incinerators or, worse, abandoned in illegal dumping places, causing a potential public health hazard. Each of these alternative methods has several limitations with respect to animal byproduct and mortality disposal, with limited space being the most obvious.

When unprocessed SRM are disposed of by methods other than rendering, their disposition is **not** regulated and the potential exists for cattle and other ruminant animals to be exposed to the same materials prohibited by the FDA. Domestic and wild ruminant

⁴ in 9 C.F.R. § 325.13

⁵ Environmental Assessment for the IFR on use of Materials Derived from Cattle in Human Feed and Cosmetics. July 9, 2004.

⁶ FAO Animal Production and Health Proceedings from Expert Consultation and Workshop on Protein Sources for the Animal Feed Industry. Bangkok April 29 – May 3, 2002.

animals may have direct exposure to unprocessed raw materials that have been improperly buried, composted or placed in landfills. As a result, these non-rendering practices could contribute to the amplification of BSE. For example, **spreading composted SRM on land used for grazing and/or hay production would not be prohibited. The potential BSE exposure of cattle grazing on such land is equal to or greater than exposure due to mixing errors on the farm, cross contamination or via poultry litter.**

Landfills. While rendering reduces volume, amendments (such as sawdust) must be added (1 part amendment to 3 parts byproduct) to compensate for the high moisture content of animal byproducts and mortalities when preparing these materials for disposal in a landfill. As a result, the total volume would be increased by approximately 25%. For example, when properly prepared, the volume of all of the animal byproducts and mortalities generated in one year would take-up approximately 25% of the existing landfill space in this country at an estimated cost of \$105 per ton⁷.

Decomposition proceeds slowly and at relatively low temperatures (130 to 150° F) in landfills which limits pathogen destruction. Landfilling animal tissues contributes to methane gas production and odors, attracts vectors (such as rats, cats, dogs, flies, etc.) and creates contact and/or inhalation exposures to humans. The United Kingdom Department of Health concluded that other disposal options are superior to landfills in reducing the risk of exposing humans to potential biological and chemical hazards, including BSE⁸. Further, the potential for increased disease among landfill workers and the transfer of pathogens to off-site locations may be increased when landfills are used for large animal disposal⁹.

However, the problems associated with putting raw SRM in landfills are alleviated if the SRM are rendered first and the MBM is disposed of in landfills. Using rendering as a pre-disposal treatment will control conventional pathogens, prevent worker exposure to disease agents, reduce BSE infectivity by 1 to 2 logarithms, reduce overall volume of the raw materials by about 75%, reduce the amount of fat going into landfill, allow value to be derived from tallow extracted from the SRM, facilitate disease surveillance and provide documentation for SRM processing and disposal.

Composting. Composting is dependent on controlled microbial fermentation to decompose animal byproducts and mortalities. Composting has limited large scale application because large amounts of carbonaceous materials are needed in order to balance the high nitrogen and moisture content in animal tissues. Considering blending and pile separation issues, approximately 27 billion cubic feet of space (more than 21 billion bushels) would be needed to compost the raw SRM generated each year¹⁰. This is equivalent to twice

⁷ Sparks Companies Inc. study on The Rendering industry: Economic Impact of Future Feeding Regulations prepared for the National Renderers Association, June 2001.

⁸ A rapid qualitative assessment of possible risks to public health from current foot and mouth disposal options. Main Report. June 2001. <http://www.doh.gov.uk/fmdguidance>

⁹ C. P. Gerba. Potential health implications from the disposal of large animals in landfills. Presentation to the Arizona Department of Agriculture. June 11, 2002.

¹⁰ T. Glanville. 2001. <http://222.ae.iastate.edu/pigsgone/>

the space needed to store all of the corn produced in this country in 2000. In addition, the spreading of composted SRM on land used for grazing or feed production is inconsistent with the intent of the FDA Feed Rule and other federal programs to prevent the potential introduction and spread of BSE in the United States. Widespread composting would dilute the integrity of the FDA Feed Rule and invalidate all existing risk assessment models.

Effective composting is difficult to manage. As a result, operators often times take short-cuts because of time and economic constraints. This results in rotting piles of animal tissues that are a source of odors and pathogens rather than a means of controlling them.

Burial is not a viable option in many states because of population density and/or the potential for ground and surface water contamination. If not done properly, burial can also create some of the same potential risks from pathogens that landfilling and composting do. Human and animal exposure to biological and some chemical (such as hydrogen sulfide) hazards is high when animal byproducts and mortalities are buried. Space is also a major limiting factor for the disposal of large quantities of these materials.

Incineration can be cost prohibitive because of the fossil fuel needed to destroy animal byproducts and mortalities. Significant amounts of ash residue are left after these materials are incinerated, creating a disposal issue. Incineration is an efficacious means of minimizing human exposure to pathogenic microorganisms. However, solid waste incinerators and waste-to-energy facilities capable of handling large volumes of waste materials are seldom located near cattle slaughter and/or production areas and are not equipped to handle raw animal tissues or carcasses. Further, as in the European Union, incineration capacity in the United States is limited¹¹ and the many regulatory challenges associated with permitting new incinerators limits construction of new facilities.

Companies that possess incinerators and/or produce energy have indicated interest in using MBM derived from SRM as a fuel source. Rendering the SRM first addresses the challenges associated with particle size reduction, handling and storage, which prevent burning the unprocessed SRM.

8. **FDA asks:** *What data is available on the extent of direct human exposure (contact, ingestion) to animal feed, including pet food?*

We are unaware of any data to support or refute this. Consumption of feed intended for livestock and poultry is unlikely. As Darling does not manufacture pet food, we will defer comment on this topic to the pet food industry.

To the degree such exposure may occur, is it a relevant concern for supporting SRM removal from all animal feed?

We defer to comments from the feed and pet food industries.

¹¹ Biocycle. December 2001. pp 42-45.

9. **FDA asks:** *What information, especially scientific data, is available to show that dedicated facilities, equipment, storage, and transportation are necessary to ensure that cross-contamination is prevented?*

Since the FDA Feed Rule was promulgated, the rendering and commercial feed manufacturing industries have moved to dedicated facilities for handling restricted use and exempted proteins to reduce commingling and cross-contamination. For facilities that continue to handle both types of animal proteins, compliance to the FDA Feed Rule requires that the facility has appropriate clean-out procedures and is able to document that such procedures have been used. These safeguards would be expected to prevent cross-contamination. We are unaware of data suggesting that further dedication of facilities, equipment, storage and transportation is necessary to insure that cross-contamination does not occur.

If FDA were to prohibit SRMs from being used in animal feed, would there be a need to require dedicated facilities, equipment, storage, and transportation?

In the event that SRM are removed from animal feed, also requiring dedicated handling facilities, equipment, storage and transportation of meat and bone meal (MBM) derived from ruminant animals will have little additional impact on reducing the risk of BSE in this country. However, it will be necessary to require dedicated collection, transport and processing of the raw prohibited materials in order to insure compliance to a SRM ban.

If so, what would be the scientific basis for such a prohibition?

Removal of SRM from animal feed will remove the potentially infectious material from the feed chain, making dedication of facilities, equipment, storage and transportation handling MBM redundant.

In addition to potentially containing the BSE agent, raw animal byproducts, including SRM, provide an excellent environment for foodborne and other conventional pathogens to grow and spread. Failure to regulate the disposal of these materials will undermine the intent of any regulation prohibiting SRM in animal feed and may contribute to the spread of BSE and conventional pathogens.

10. **FDA asks:** *What would be the economic and environmental impacts of requiring dedicated facilities, equipment, storage, and transportation?*

There is no need to require dedicated facilities, equipment, storage and transportation for MBM use in feed, if the SRM are removed. Darling International Inc. does not operate any facilities that produce both restricted use and exempt MBM, as defined by the FDA Feed Rule. Requiring dedicated transport for restricted use MBM would be costly to the industry. Dedicated transport would significantly reduce our access to independent truckers who frequently haul the MBM we produce one-way and haul another commodity on the return trip. Back-hauling in this way is a common practice for all aspects of the commercial feed industry. Dedicated transport would also severely restrict our access to leased rail cars. As a result, we would be required to almost double the number of units in our present fleet in order to transport finished products. At present, most of our existing fleet is dedicated to

transporting raw animal byproducts and mortalities from farms or meat processors to Darling facilities for processing

Darling International Inc. recognizes and supports the need for dedicated facilities, equipment, storage and transportation to handle the raw SRM, should they be banned from animal feed. Such dedication is essential for the FDA to enforce a ban on SRM going into animal feed. However, it will be difficult to dedicate certain existing facilities to the disposal of SRM without regulations that insure that these materials are properly disposed of.

11. FDA asks: What information, especially scientific data, is available to demonstrate that clean-out would provide adequate protection against cross contamination if SRMs are excluded from all animal feed?

Clean-out procedures are not a concern if SRM are banned from animal feed. However, clean-out procedures would be beneficial for facilities that process and dispose of SRM. Darling International Inc. encourages the FDA to adopt the clean-out procedures described in the agencies compliance guide for renderers¹². In this document, the agency suggested clean-out procedures to prevent commingling and cross-contamination. Clean-out was defined as physical cleaning, flushing, sequencing, or other means, either alone or in combination with separation measures that are adequate to prevent carryover of prohibited materials into non-prohibited material. Documentation needed to verify that clean-out occurred was also described.

Following discovery of a case of BSE in the State of Washington in December of 2003, the procedures described in the appropriate Example Processing Options section of the aforementioned compliance guide¹³ were used to allow rendering companies that had received offal from the infected cow or recalled meat to resume production following complete flush-out and clean-out of equipment. Such procedures should also be adequate for SRM, especially those tissues that have not been tested for BSE and may not contain the infectious agent.

12. FDA asks: What information, especially scientific data, supports banning all mammalian and avian MBM in ruminant feed?

To our knowledge, there is no scientific data to support banning all mammalian and avian MBM in feed. The only reason to consider such a ban appears to be for compliance purposes. Even in the United Kingdom and the European Union, where the prevalence of BSE was high, there was no scientific justification for banning animal proteins from animal feed. Officials in those countries admitted that leakage and the unscrupulous blending of prohibited materials with exempted materials was occurring and banning all materials was necessary to insure compliance to their feed restrictions

¹² FDA GUIDANCE FOR INDUSTRY 67 – SMALL ENTITIES COMPLIANCE GUIDE FOR RENDERERS (February 1998)

¹³ *Id.*

The FDA has reported exceptional compliance to the FDA Feed Rule, based on the agency's own data¹⁴. These results indicate that compliance is especially high among renderers. Of the 2,901 active feed manufacturing and rendering firms handling prohibited materials, a compliance rate of 96.3% was reported for their most recent inspections.

If SRM are banned from feed, then there is no reason to ban all mammalian and avian proteins in ruminant feed.

13. FDA asks: *If SRMs are required to be removed from all animal feed, what information, especially scientific data, is available to support the necessity to also prohibit all mammalian and avian MBM from ruminant feed, or to otherwise amend the existing ruminant feed rule?*

Removal of SRM from animal feed will make it unnecessary to also prohibit all mammalian and avian MBM from ruminant feed or otherwise amend the existing Feed Rule. Regulating the disposal of SRM so they do not find their way back into animal feed will essentially remove all potential BSE infectivity from all MBM, even MBM derived from ruminant animals. **Failure to regulate SRM disposal will make it difficult to verify that these materials did not enter the feed chain and that ruminant animals were not potentially exposed to the BSE agent.** As a result, additional prohibitions might be necessary at a later date.

14. FDA asks: *What would be the economic and environment impacts of prohibiting all mammalian and avian MBM from ruminant feed?*

Such a far reaching ban has never been seriously considered in the United States. Sparks Companies Inc.¹⁵ reported that a ban on all mammalian proteins from ruminant feed would cost the rendering industry in excess of \$100 million in lost revenue. Such a ban would also cause significant changes in the overall structure of the rendering industry and accelerate consolidation within the industry and cause many independent rendering companies to close, leaving many farmers, ranchers and small processors without access to rendering facilities.

The impact of also banning avian proteins, such as feather meal and poultry MBM from ruminant feeds were not considered by Sparks Companies Inc in their 2001 study. Because feather meal is an important by-pass protein for the dairy and fed cattle industries, such a ban would also have a significant impact on these industries, in addition to the rendering industry. However, Sparks estimated that prohibitions against the use of all animal proteins in all animal feeds (ruminant and nonruminant) would reduce the market price paid for cattle (\$15.49/head), pigs (\$3.22/head), broiler chickens (\$0.07/bird) and turkeys (\$0.33/bird). These costs are based on the complete loss of economic value for animal proteins (not animal fats) and assume that rendering services will continue to be available and utilized. They do not address the potential costs associated with either a major reduction in or the complete

¹⁴ July 2004 update on Ruminant Feed (BSE) Enforcement Activities. CVM Update. July 29, 2004.

¹⁵ Sparks Companies, Inc. The Rendering Industry: Economic Impact of Future Feeding Regulations. June 2001.

loss of rendering services to the livestock, poultry and meats industries. Economic impacts of this magnitude are not currently available.

15. FDA asks: *Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants?*

We are unaware of any direct evidence linking BSE transmission to bovine blood or blood products. Darling International Inc. handles very little blood and defers further comment to the blood and blood products industry.

16. FDA asks: *What information is available to show that plate waste posed a risk of BSE transmission in cattle and other ruminants?*

Darling is unaware of any proven or suggested link between plate waste and BSE. Since meat and meat products presented for human consumption are free of SRM and downer cattle, then it would logically follow that plate waste would not present a risk of BSE.

17. FDA asks: *If FDA were to prohibit SRMs from being used in animal feed, would there be a need to prohibit the use of poultry litter in ruminant feed?*

No – if SRM are removed, then the MBM fed to poultry would not contain any potentially infectious material, making the poultry litter safe, even if it contained spilled feed containing ruminant derived MBM.

If so, what would be the scientific basis for such a prohibition?

Even if SRM are not banned, the theoretical transmission of BSE to cattle via poultry litter is difficult to demonstrate. MBM is typically added to poultry diets in relatively small amounts (5% or less), resulting in significant dilution in the poultry feed. Even if a fully infected cow were rendered, little infective material would be present in the feed because of this dilution and the reduction in infectivity (1 to 2 logs) due to rendering. Spilled feed in the poultry litter would be further diluted, making it difficult for cattle to be exposed to a full ID 50.

18. FDA asks: *What would be the economic and environmental impacts of prohibiting bovine blood or blood products, plate waste, or poultry litter from ruminant feed?*

Darling handles only limited amounts of blood meal and does not handle plate waste or poultry litter. Therefore, we defer comment to industries dealing in these materials.

19. FDA asks: *Is there any information, especially scientific, showing that tallow derived from the rendering of SRMs, dead stock, and non-ambulatory disabled cattle poses a significant risk of BSE transmission if the insoluble impurities level in tallow is less than 0.15 percent?*

The FDA recently published an IFR indicating that tallow containing less than 0.15% insoluble impurities is safe for use in human food and cosmetics¹⁶. It logically follows that tallow meeting this tolerance should also be allowed for use in feed. Further, a tolerance of 0.15% insoluble impurities is consistent with international standards for tallow. However, Darling International Inc. feels that the American Oil Chemist Society (AOCS) Official Method Ca 3a-46 should be the preferred method for detecting insoluble impurities in tallow and not the method specified to detect hexane insoluble impurities (from the 5th Ed. of the Food Chemicals Codex) in the IFR. Compared to the Food Chemicals Codex method, the AOCS Official method is: 1) already standardized, 2) routinely used by the industry and commercial laboratories, 3) requires the use of smaller quantities of solvents, 4) the per samples cost is much lower (about 1/10th to 1/20th) and 5) the AOCS method uses standard equipment and glassware already available in most commercial laboratories.

20. FDA asks: *Can SRMs be effectively removed from dead stock and non-ambulatory disabled cattle so that the remaining materials can be used in animal feed, or is it necessary to prohibit the entire carcass from dead stock and non-ambulatory disabled cattle from use in all animal feed?*

Darling International Inc. believes that the removal of SRM from dead and non-ambulatory cattle is a complex issue. The ability to confidently remove the SRM from dead cattle is dependent on the degree of decomposition and the condition of the carcass when it arrives at the rendering facility. It is virtually impossible to remove SRM from a carcass that has had its back broken during loading/unloading and/or is partially decomposed.

The rate of decomposition is positively correlated with ambient temperature (decomposition advances at an increasing rate as temperature increases) and is influenced by the condition of the carcass (hide intact or split), degree and composition of gastrointestinal fill, etc.

Facilities equipped with refrigerated coolers, freezers and a rail system for handling carcasses may be able to remove SRM from those carcasses that are relatively fresh when they arrive at the rendering plant. Only rendering plants that harvest meat for the pet food market are still equipped with this type of equipment.

Even for these pet food plants, provisions will have to be made to verify that the SRM were removed from the dead cattle in order for the facility to be in compliance with a SRM ban. This will require on-site supervision by a credentialed federal inspector, such as an FSIS veterinarian.

¹⁶ Interim Final Rule: Use of Materials Derived from Cattle in Human Food and Cosmetics docket No. 2004N-0081. Federal Register. Vol. 69. No. 134. 42256-42274.

21. FDA asks: *What methods are available for verifying that a feed or feed ingredient does not contain materials from dead stock and non-ambulatory disabled cattle?*

We are not aware of any methods to detect bovine MBM in animal feed that are sufficiently precise, economical, and currently ready for commercialization. Since the dead and non-ambulatory cattle will have the same tissues as will be found in other animal byproducts that we expect will still be allowed in feed, it is unlikely that such a method will be developed. As discussed in questions # 5, the FSIS method used to test for CNS tissue was developed for uncooked meat. Testing the raw material for CNS tissue is most likely not an option, because the large volume and diverse types of tissues present make it difficult to obtain a representative sample.

As discussed in our comments to questions # 5, the most effective method for verifying that dead stock and non-ambulatory cattle has been removed and not rendered to make MBM is to regulate the disposal of these materials. Such regulations will give the agency full control over the collection and disposal of dead and non-ambulatory cattle as a means of verifying that these materials did not enter the feed chain.

22. FDA asks: *What would be the economic and environmental impacts of prohibiting materials from dead stock and non-ambulatory disabled cattle from use in all animal feeds?*

In the economic assessment published with the IFR which banned SRM, non-ambulatory cattle and dead cattle from human food and cosmetics, the agency estimated that only 17%, on average, of all dead cattle are rendered each year in this country¹⁷. This grossly understates the importance of the rendering industry in collecting, processing and disposing of cattle mortalities. Sparks Companies Inc. estimated that 45% of dead cattle were rendered in 2000¹⁸. We believe that between 40% and 45% of all cattle mortalities are currently being rendered in the United States.

The National Renderers Association has commissioned Informa Economics (formerly known as Sparks Companies Inc.) to update their previous study on cattle mortality disposal issues. We refer the agency to comments submitted by the NRA for the economic and environmental impact of banning dead cattle from feed.

More than 2.5 billion pounds of dead and non-ambulatory cattle occur each year in the United States. The total grows to almost 4 billion pounds when the SRM from slaughter cattle are included. If a plan is not developed to insure that these materials are properly disposed of, then the disposal of more than 2.4 billion pounds (assuming 42% of dead cattle are rendered) of raw animal tissues will become unregulated. Without regulations, these

¹⁷ Environmental Assessment for the IFR on use of Materials Derived from Cattle in Human Feed and Cosmetics. July 9, 2004.

¹⁸ Sparks Companies Inc. Report on Livestock Mortalities: methods of Disposal and Their Potential Cost, Prepared for the National Renderers Association, March 2002.

materials will be disposed of using the cheapest method available, which is usually abandonment.

Regulated disposal would insure that the materials currently being rendered are disposed of safely and responsibly and the 1.4 billion pounds of cattle carcasses that are not rendered and subject to improper disposal will also be controlled. Given the present lack of control over dead cattle disposal (as evidenced by the volume of cattle material not rendered) and the extraordinarily high compliance rate to the FDA Feed Rule, **federal agencies should not assume that any future cases of BSE in the United States occurred solely because of cross-contamination and/or on-farm mixing errors.**

APHIS veterinarians have taken few samples for BSE surveillance on-farm. Most samples from dead cattle have been and continue to be taken at rendering facilities. Therefore, the incidence of BSE in the United States cattle population may be uncertain and the possibility that one or more cattle died from BSE and was disposed of inappropriately exists. Regulations, such as the rule in Appendix A, would insure that most dead cattle are available for disease surveillance and properly disposed of.

23. APHIS asks: *What other innovative solutions (other than converting SRM into renewable energy) could be explored?*

The first concern with SRM and cattle mortalities should be to insure that these materials are safely and responsibly collected, transported and disposed of. Regulations to insure that these materials are handled correctly are needed. Composting has been encouraged by many state agencies and universities. However, because of the capital investment and expertise needed to compost correctly, farmers and small operators typically choose low-investment composting systems that are also management intensive. Such systems can be found throughout the Midwest usually as piles of rotting carcasses that threaten human and animal health and cause damage to the environment. The agency would be well advised to develop regulations requiring that any materials that are prohibited from use in feed be disposed of by licensed operators using methods that meet uniform standards for biosecurity, traceability and environmental protection. One such model regulation is attached (Appendix A) to these comments.

Darling International Inc. also agrees with the concerns expressed to the Secretary by the National Renderers Association in their letter of May 28, 2004, regarding the May 18, 2004 *Federal Register* notice announcing fund availability to provide guaranteed loans for developing renewable energy systems using diseased livestock and their byproducts. While USDA showed resourcefulness in developing this type of program to facilitate productive private disposal of SRM from non-ambulatory disabled livestock, the construction of the program effectively and totally eliminates the rendering industry from participation.

USDA has structured the program so narrowly as to work at cross-purposes to the department's stated goal, i.e. safe, efficient disposal of potentially infective SRMs while recycling otherwise valueless commodities for alternative energy generation.

The rendering industry is the recognized leader in alternative animal byproduct-based fuel development through its investigation of, investment in, and use of various U.S. and

global technologies – extant and evolving – which permit refinement of animal fats and oils into biodiesel.

However, this NOFA ignored that commitment, implicitly discounting rendering as the sole regulated industry with the expertise to handle, dispose and process SRM. Renderers possess the technology, equipment and expertise necessary to handle this vital role in U.S. BSE risk mitigation. Our companies comprise the only industry already permitted, inspected – with HAACP procedures in place – and with the infrastructure to identify, locate, transport, handle and process nonambulatory and dead livestock.

Instead of exploiting this expertise, USDA contemplates bringing new, inexperienced companies to the SRM removal system, a move which will unnecessarily complicate and delay the important goal of enhanced BSE mitigation. Already we've received reports of a "cottage industry" springing up around the country, individuals seeking to collect dead animals at a price, the ultimate disposal being landfill – an option, in our professional opinion, to be wholly unacceptable from both disease mitigation and environmental standpoints, and one without official sanction in the federal BSE program.

Darling encourages the agency to adopt a comprehensive plan similar to the model described in Appendix A and enhance funding to discover and develop new appropriate uses for SRM, dead cattle and non-ambulatory disabled cattle that will add value.

24. APHIS asks: *When and under what circumstances should the program (animal identification) transition from voluntary to mandatory?*

The ability to successfully trace animals should another case of BSE or other foreign animal disease, such as Foot and Mouth Disease, be reported in the United States will be directly proportional to the degree of producer participation in a voluntary animal identification program. The only way to insure reliable and relatively accurate traceability is to require mandatory participation.

25. APHIS asks: *What species should be covered (by animal identification), both initially and in the longer term?*

While BSE affects only cattle, other foreign animal diseases, such as Foot and Mouth Disease, which are potentially more devastating to the United States livestock industry, affect several species. Therefore, including all farmed animal species in the animal identification program will be an important disease control and eradication tool.

Specifically, should the initial emphasis be on cattle, or also cover other species?

Since BSE has served as the principal stimulus to finally organize a national animal identification program, it is logical that it should begin with cattle. However, other species should be developed soon after, using appropriate portions of the cattle program as a model.

If so, which?

Cattle should be given the initial priority, but a program for other major species should be developed on something close to a parallel track.

Which species should be covered by the program when it is fully implemented?

All farmed animal species, including farmed cervids and others that are either susceptible to a transmissible spongiform encephalopathy (TSE) or serve as reservoirs for other foreign animal diseases should be included. A national animal identification program has obvious production and herd or carcass improvement potential that can benefit all farm animal producers.

What priority should be given to including different species?

All species should be given similar priorities for inclusion in the program. However, size and economic importance of the national herd or flock should be used to prioritize the order in which an animal identification program is developed for each specie.

26. **APHIS, FDA and FSIS asks:** *How can training and educational materials be designed or improved to meet the needs of multiple audiences with variable levels of scientific training?*

Adequate resources already exist through the Agricultural Research Service, the Agricultural Extension Service and other agencies and organizations having research/outreach programs. Land grant universities also provide a tremendous pool of resources that could be tapped to develop and deliver educational materials to a variety of different audiences.

27. **APHIS, FDA and FSIS asks:** *How can Federal Government increase access to these materials?*

State and federal workshops, extension service programs as well as factsheets and tutorials that is readily available to the public via the internet, public TV and other media.

28. **FDA asks:** *Should FDA include exemptions to any new requirements to take into account the future development of new technologies or test methods that would establish that feed does not present a risk of BSE to ruminants?*

The agency should provide for the review, evaluation and possible acceptance of new technologies as they become available. We encourage the agency to publish the criteria that will be used to evaluate any such technologies. A similar provision was provided in the FDA Feed Rule, but the criteria that new products or technologies had to meet in order to gain an exemption to the Feed Rule were never published.

29. FDA asks: *If so, what process should FDA use to determine that the technologies or test methods are practical for use by the feed industry and ruminant feeders and provide scientifically valid and reliable results?*

We are unaware of any such technologies that are nearing commercialization. However, new technologies are being developed that may prove to be beneficial. One such technology is the development of an aggressive keratinase enzyme that is reported to inactivate the BSE agent by hydrolyzing the protein to the point that it is no longer functional (Jason Sheah, North Carolina State University). For more information on this emerging technology please see the abstract in the 2004 Journal of Animal Science (volume 82, Supplement 1, page 78, Abstract # 2).

30. FDA asks: *Do FDA's existing authorities under the Federal Food, Drug, and Cosmetic Act (that address food adulteration and misbranding) and under the Public Health Service Act (that address the prevention and spread of communicable diseases) provide a legal basis to ban the use of SRMs and other cattle material in nonruminant animal feed (e.g. feed for horses, pigs, poultry, etc.) notwithstanding that such materials have not been shown to pose a direct risk to nonruminant animals?*

We agree that the FDA has the authority to ban the use of SRM in feed for nonruminant animals.

More specifically, under FDA's existing legal authorities would the potential occurrence of on-farm feeding error, of cross contamination of ruminant feed (including pet food) provide a basis to ban SRMs and other cattle materials from all animal feed?

The current state of the science appears to demonstrate that certain animals, such as porcine and avian species, do not amplify the BSE agent even if they ingest it, and do not themselves appear to be susceptible to contracting the disease ("non-susceptible species"). However, BSE research continues to evolve and the science has not ruled out the possibility that these species could pass on the disease agent in their tissues if ingested by other species, including humans. If these animals were to ingest SRM from a BSE-infected cow and harbor the infective agent within their tissues, and if that infective agent were to be ingested by a susceptible species, such as a ruminant or human, the possibility may exist that the susceptible species could contract the disease. As such, the tissues of such "non-susceptible" animals having ingested infective SRM, when those tissues are used as food or feed ingredients, would be adulterated under Section 402(a)(1), (a)(2)(A) or (a)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("the Act") (21 U.S.C. §342(a)(1), (a)(2)(A) or (a)(2)(C)) as containing a deleterious substance that may render the feed material injurious to health, an added deleterious substance or an unsafe food or feed additive. Feed materials that could cause such adulteration, i.e., infective SRMs, would also be adulterated under Section 402(a)(1). CVM has the power to prohibit the inclusion of SRM in animal feed under its general powers pursuant to the Act. The simplest potential mechanism to regulate these adulterating products is to amend 21 C.F.R. Part 589 to prohibit the use of SRM in animal feed.

Additionally, SRM could be regulated as feed additives under the 1958 Food Additives Amendment. Feed additives must be shown to be safe before they are permitted to be used in

food or feed. SRM that may be infective clearly cannot be generally recognized as safe. Indeed, FSIS has already so concluded when it removed SRM from human food.

Significantly, CVM has the power to declare SRM to be adulterated or to be feed additives that are not GRAS for use in animal feed, or to declare adulterated the food or feed in which they are incorporated, before any actual harm occurs. In the preamble to the Federal Register Notice publishing the final version of Section 589.2000, CVM noted that the Act does not require that FDA wait until actual harm occurs before declaring a substance to be non-GRAS.¹⁹ All that is required is information “that the use of [a particular substance in] feed may not be safe or that there is no expert consensus that the use of the substance is safe.”²⁰ Thus, CVM may use the Act as a whole, including the 1958 Food Additives Amendment, as a tool to prevent harm to the public health before it occurs.²¹ In the final ruminant feed ban rule, for example, FDA concluded that a consensus did not exist that the use of protein derived from mammalian tissues is safe for use in ruminant feed.²²

Whichever mechanism CVM chooses to use, the Center is able to prohibit inclusion of possibly infective SRM in the food or feed chains.

31. FDA asks: *Are there other, related legal issues on which FDA should focus?*

In the event that FDA bans SRM, dead cattle and non-ambulatory disabled cattle from feed, federal agencies will essentially lose all control and regulatory oversight over the disposition of these materials. FDA is encouraged to work with APHIS in developing regulations (such as those described in Appendix A) to insure that these materials are disposed of in a biosecure manner that protects human and animal health, is environmentally friendly, and provides traceability/verification of disposal.

Advice from our legal counsel suggests that the FDA and APHIS each have the authority to regulate the disposal of animal byproducts and mortalities that are banned from feed.

FDA has the authority under section 361 of the Public Health Service Act (PHS act) (42 U.S.C. section 264). Section 361 of the PHS act gives the Secretary of Health and Human Services the authority to make and enforce regulations to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the States or from one State to another State. Both FDA and the Centers of Disease Control and Prevention have issued regulations under section 361 of the PHS act, including most recently in November 2003, 21 C.F.R. section 1240.63 and the corresponding CDC regulation 42 C.F.R. section 71.56 to control the introduction and spread of the monkeypox virus in the United States.

¹⁹ 62 Fed. Reg. 30936, 30949 (June 5, 1997).

²⁰ *Id.*

²¹ *Id.* (citing *United States v. Ewig Bros. Co.*, 502 F.2d 715, 721 & n.24 (7th Cir. 1974), *cert. denied*, 420 U.S. 945 (1975); S. Rep. No. 2422, 85th Cong., 2d Sess. 1-3 (1958); H.R. Rep. No. 2284, 85th Cong., 2d Sess. 1 (1958)).

²² *Id.*

APHIS has the authority to regulate how animal producers may move and dispose of dead animals, as provided in the Animal Health Protection Act of 2002 (Subtitle E of the Farm Security and Rural Investment Act of 2002, Pub. L. 107-171). Section 10406 states that the Secretary of Agriculture may prohibit or restrict “the movement in interstate commerce of any animal, article, or means of conveyance if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction or dissemination of any pest or disease of livestock.” Similarly, Section 10409 states that the Secretary “may carry out operations and measures to detect, control, or eradicate any pest or disease of livestock...including animals at a slaughterhouse, stockyard, or point of concentration.”

32. FSIS asks: *What measures are necessary to prevent cross contamination between carcasses?*

Darling International Inc. does not slaughter cattle or process meat and defers this question for the meat packing industry to address.

33. FSIS asks: *In establishing that predominantly slaughter cattle over 30 months of age and older, are additional sanitation requirements necessary to prevent edible portions of carcasses from being contaminated with SRMs?*

Darling International Inc. does not slaughter cattle or process meat and defers this question for the meat packing industry to address

34. FSIS asks: *Should FSIS provide an exemption for “BSE free” countries or countries with some other low-risk BSE designation?*

Yes – FSIS should treat other countries with the same courtesies as we would expect for products exported from the United States, provided such courtesies are consistent with our own domestic requirements and expectations.

35. FSIS asks: *If FSIS were to exempt “BSE free” countries from the provisions of the SRM rule, what standards should the agency apply to determine a country’s BSE status?*

Standards should be consistent with standards that we would expect the trading partner to use for United States produced products.

36. FSIS asks: *How would FSIS determine that country meets such standards?*

International standards that are uniformly followed would be beneficial.

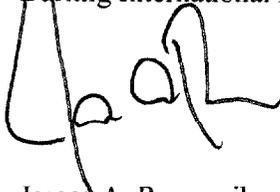
For example, should it rely on third party evaluations, such as OIE, or conduct its own evaluation?

Ideally, working with a third party, such as the OIE could contribute to harmonization of the standards used to determine the BSE status of a country and facilitate the sale and movement of bovine derived materials on the global market.

The problem with working with a third party, such as OIE, is reconciling differences and uniformly applying criteria used to evaluate the BSE status of other countries. Differences in testing regimens to determine BSE prevalence, differing definitions of SRM tissues and age classifications used to determine which SRM are to be removed must be resolved.

In summary, Darling International Inc. wants to encourage the Agency to carefully consider the impact new regulations will have upon the viability and survivability of the rendering industry, which serves a vital role in controlling and eradicating animal diseases in this country. **We also ask FDA to seriously consider creating policy and regulations that will insure that SRM, dead cattle and non-ambulatory cattle are disposed of properly. A model regulation is attached in Appendix A as an example.** Without a comprehensive disposal plan, regulations that ban raw animal byproducts and mortalities from feed will exacerbate the improper and illegal disposal of the raw materials. In effect, efforts to avoid the risk of BSE in the U.S. will inadvertently weaken the rendering industry and pathogenic agents that have been controlled by rendering in the past will create real biosecurity threats to both animals and humans.

Respectfully,
Darling International Inc.



James A. Ransweiler,
Executive Vice President,
Sales and Marketing



C. Ross Hamilton, Ph. D.
Director Research & Nutritional Services

Enc.: Appendix A

Cc.: Tom Cook, President
National Renderers Association

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 C.F.R. sections 16.1 and 1240.70

Proposed Regulations; Control of Communicable Diseases Involving Animal Materials Restricted From the Human Food and/or Animal Feed Chain

AGENCY: Food and Drug Administration.

ACTION: Interim Final Rule

SUMMARY: The Food and Drug Administration (FDA) is publishing an interim final rule that will require the disposal of Restricted Animal Materials (RAMs), which are defined as animal-sourced materials that are prohibited from use in human food and/or animal feed and includes any material from which such prohibited material cannot be adequately separated. These regulations are designed to reduce the risk that such materials may serve as potential pathways for the spread of Bovine Spongiform Encephalopathy (BSE), other Transmissible Spongiform Encephalopathies (TSEs) and other communicable diseases in the United States.

DATES: We will consider all comments that we receive on or before [date].

ADDRESSES:

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Background

In an Advance Notice of Proposed Rulemaking published in the Federal Register on January 21, 2003, the Animal and Plant Health Inspection Service (APHIS) solicited public comment to help it develop approaches to control the health risks posed by dead and nonambulatory animals, including most importantly the risk that such animals may be potential pathways for the spread of BSE. (68 Fed. Reg. 2703). The APHIS ANPR discussed at length the results of a 2001 risk assessment conducted by the Harvard Center for Risk Analysis on the possibility of BSE entering and becoming established in the U.S. (the Harvard Study). Since the publication of the proposal in January 2003, BSE-positive cows have been found in the U.S. and Canada. As a

result of those events, authorities have banned the inclusion of certain RAMs in the human food supply.

In the January 2003 Notice, APHIS sought comment on whether it is possible to ensure “rendered products from possibly-infected dead stock would all be used in ways that would not spread [Transmissible Spongiform Encephalopathies (TSEs)].” (68 Fed. Reg. 2708). One of the suggestions proffered by the authors of the Harvard Study designed to prevent the spread of BSE in the U.S. ruminant population included separately disposing of all non-ambulatory cattle, Specified Risk Material (SRMs) and dead animals containing such SRMs.

Bovine Spongiform Encephalopathy and Rendering

BSE is a TSE that has been shown to infect cattle. Since its first documentation in the United Kingdom in 1986, BSE has spread to approximately 20 other European countries, Canada, Israel, Japan, Oman and, in December 2003, the United States. Other TSEs have also affected U.S. livestock and wildlife, including scrapie in sheep and goats and chronic wasting disease in both captive and free-ranging elk and deer. In many ways, TSE diseases present a more difficult problem than other animal diseases with regard to controlling the spread of disease through Dead Stock¹. This is due to the nature of TSE diseases, the historical lack of live-animal tests for them, and the extreme hardiness of TSE agents.

In European cattle populations, research has shown that BSE is present in a higher percentage of nonambulatory and dead livestock than in the general cattle population. An animal at the point of death from BSE is also generally in its most infectious state, with a high concentration of the BSE agent in certain tissues. Studies by the USDA and independent researchers concur with the Harvard Study that non-ambulatory cattle and dead cattle that were rendered and allowed into the animal feed chain would pose a risk of spreading BSE. In January 2001, the Food and Agriculture Organization of the United Nations issued a press release urging countries to take steps to reduce BSE risks; one of the recommended practices was correct disposal of animal mortalities.

Because, by their nature, non-ambulatory cattle and Dead Stock include many animals that suffered from communicable diseases, they represent a significant pathway for spread of disease if they are not handled or disposed of with appropriate safeguards. Over time, USDA and industry have developed methods to mitigate, if imperfectly, the risks presented by Dead Stock affected by the older, better-known animal diseases.

The BSE agent is resistant to destruction by standard cooking practices and sterilization procedures. The rendering processes used in the United States, however, will reduce the infectivity of a TSE agent in the rendered material by a factor of 1 to 3 logs depending on the

¹ Sometimes referred to as “on-farm deaths,” Dead Stock are livestock that die or are killed other than by slaughter. The only Dead Stock covered by this rule are those species containing RAMs.

process used.² The rendering process stabilizes animal byproducts with heat, which evaporates the water contained in tissues and provides a sterilizing effect. While the end products from rendering have been used as feed ingredients in the past, the fats also have other, non-food/non-feed uses, such as in biodiesel fuels. These materials derived from disposal rendering of RAMs could continue to be put to these non-food/non-feed uses, as specified in the regulations. The animal proteins from RAMs that previously have been used in feed can be diverted from feed and/or destroyed using documented and verifiable methods. It is possible that new non-feed uses may be developed for this material as well. In that case, the proteinaceous product of disposal rendering may also be put to these new uses, if approved by the Commissioner of FDA (“Commissioner”).

Disposal rendering provides a mechanism for sharply reducing the volume of potentially disease-carrying animal byproducts and mortalities produced in the United States each year,³ while increasing the stability of materials that may pose a biological hazard. Controlled incineration and alkaline digestion are also effective pathogen destruction disposal methods. Complete incineration removes moisture and combusts the organic matter, leaving the inorganic residue or ash and potentially reducing the volume of RAMs. Such volume reduction can not be achieved with alkaline digestion without drying the digest effluent. This is because chemicals must be added in order to achieve alkaline digestion, which increases moisture content and overall volume of the RAMs.

The etiology of TSE agents is not completely understood, but the leading theory suggests the agents to be an abnormal form of the prion protein. Therefore, disposal methods that destroy the amino acids necessary to make up a complex protein are assumed to deactivate TSE agents. This correlation has been used in the United Kingdom to assess the effectiveness of incineration by testing the ash residue for amino acid nitrogen.⁴

The exposure of proteins to alkaline treatment will break the peptide bonds to produce peptides consisting of varying numbers of amino acids as intermediate products. If the alkaline treatment continues long enough, free amino acids will be produced as more peptide bonds are broken. Applying heat in combination with the alkaline treatment will cause racemization of some amino acids and/or destroy most other amino acids.⁵ Alkali in combination with heat is acknowledged as an effective means of reducing the infectivity of TSE agents and, based on pilot scale studies;

² A 1-log reduction is reduction by a factor of 10, 2 logs a reduction by a factor of 100, 3 logs by a factor of 1000, etc.

³ As noted in the January 2003 APHIS Notice on this topic, rendering reduces the volume of material by 64 percent. *See* 68 Fed. Reg. 2708.

⁴ D. M. Taylor and S. L. Woodgate. 2003. Rendering practices and inactivation of transmissible spongiform encephalopathy agents. *Rev. sci. tech. Off. int. Epiz.* 22(1): 297-310.

⁵ Waste Reduction Inc. 2002 Biological waste management by alkaline hydrolysis. Technical Data Monograph. <http://www.wr2.net/technicaldata>.

the commercial scale application of these approaches is expected to be effective.⁶ Even though the processing parameters necessary to inactivate TSE agents have been studied, minimum specifications for the temperature, pH and digestion time to be used when digesting RAMs have not been agreed upon. Such process conditions will be specified by the Commissioner when confirmatory testing is completed. The digest effluent may contain high levels of nitrogen and other chemical elements, such as sodium, potassium and others, in addition to large amounts of moisture. Therefore, effluent discharges, including dried effluent, must meet all applicable regulatory requirements.

Other methods of disposal of animal mortalities and RAMs, such as burying, composting, burning in pyres and abandoning the materials, pose greater and potentially significant health and environmental risks. Although some of the methods may reduce the infectivity of the BSE agent, each method is highly susceptible to user error, potentially spreading the disease. For example, direct exposure to improperly buried Dead Stock and consumption of feed or grass contaminated by run-off that passed over such animals are routes of potential disease exposure of the BSE agent and conventional pathogens. Composting is largely unregulated today and fails to kill pathogens when done incorrectly; in addition, it poses the same direct exposure risk posed by buried stock. Finally, the low cost of abandonment makes it a popular alternative today, but it poses obvious threats to human and animal health and the environment.

BSE in the U.S. and prohibition of RAMs in the food and feed chain

On December 23, 2003, the Secretary of Agriculture announced that a BSE-positive cow had been detected in the United States. On December 30, 2003, the Secretary of Agriculture declared SRMs, small intestine from all cattle, material from nonambulatory disabled cattle, and mechanically separated beef to be inedible and thereby prohibited their use in human food. On January 26, 2004, FDA announced that it was enacting new safeguards to prevent the spread of BSE in the United States. Pursuant to that announcement, FDA enacted an Interim Final Rule on July 14, 2004 prohibiting the inclusion of SRMs, small intestine from all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption and mechanically separated beef cattle from human food and cosmetic products. At the same time, FDA and APHIS published a joint Advance Notice of Proposed Rulemaking ("joint ANPR") raising 36 questions regarding additional measures that may be taken to prevent the spread of BSE in the United States. Certain of those questions related to the feasibility of prohibiting certain materials, including SRMs and other cattle-derived materials, from the animal feed supply.

After consideration of the comments received in response to the joint ANPR, FDA prohibited _____ from the animal feed supply. _____ will be referred to in this Interim Final rule as Restricted Animal Materials (RAMs). Because these RAMs will no longer be marketable in animal feed, at least some of the materials currently do not have a market and will have to be disposed of. Others have non-feed, industrial uses. Both

⁶ Opinion of the European Commission Health and Consumer Protection Directorate-General Scientific Steering Committee adopted May 16, 2002.

types of material, if not properly processed, have the potential to spread communicable diseases to man and other animals. Unprocessed material derived from cattle, such as brain, spinal cord, and small intestine, can potentially spread not only BSE but more common foodborne pathogens, such as *Clostridium perfringens*, *Listeria* species, including *L. monocytogenes*, *Campylobacter* species, including *C. jejuni*, *E. coli*, and *Salmonella* species, and the pathogens that cause brucellosis, anthrax, pseudorabies, vesicular stomatitis, West Nile Virus and other important livestock and zoonotic diseases which can result in a threat to human and animal health. Proper disposal, by rendering, incineration or alkaline digestion, will minimize this disease transmission risk. For those RAMs that can be processed into other end uses, such as tallow and tallow derivatives, prior processing is required to minimize the disease-transmission potential of these materials.

The interim final rule would require the regulated disposal of RAMs. Using federally licensed and dedicated facilities to process RAMs will reduce the likelihood that prohibited and/or infected material may be included in animal feed. If materials are treated to disposal in the same facility as materials to be rendered and incorporated into animal feed, the possibility of mix-ups or commingling exists, even under the most stringent procedures or with the best of intentions. FDA therefore requires that disposal be conducted only at licensed disposal facilities, as described in the interim final rule. A disposal facility will need to be a facility that is separate and distinct from any other establishment. With the exception of part-time disposal facilities, a disposal facility will be prohibited from handling material destined for inclusion in animal feed. Part-time disposal facilities will be required to perform the clean-out procedures specified in the regulations. Adequate recordkeeping and proper disposal of RAMs will also be critical disease-containment tools for BSE.

Section 361 of the Public Health Service Act (PHS act) (42 U.S.C. section 264) serves as the legal authority for this regulation. Section 361 of the PHS act gives the Secretary of Health and Human Services the authority to make and enforce regulations to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the States or from one State to another State. As we explain in the Legal Authority section of this document, both FDA and the Centers for Disease Control and Prevention have issued regulations under section 361 of the PHS act, including most recently in November 2003, 21 C.F.R. section 1240.63 and the corresponding CDC regulation 42 C.F.R. section 71.56 to control the introduction and spread of the monkeypox virus in the United States.

The interim final rule

The interim final rule will standardize the disposal of RAMs according to uniform requirements. This will permit the development of a disposal infrastructure to handle materials that cannot be used in human food and/or animal feeds. Dedicated processing of such materials will reduce the biological hazard they pose.

FDA proposes to license "Disposal Facilities." These dedicated facilities will collect, process, store and, if necessary, dispose of RAMs in accordance with air, water and solid waste standards applicable to such operations. With the limited exception of part-time Disposal Facilities, dedicated facilities will not process animals and byproducts that are destined for use in the animal feed supply. Once there is a network of licensed Disposal Facilities equipped to handle

the demand for disposal services, disposal of RAMs by other than rendering, controlled incineration, or alkaline digestion will be prohibited. The interim final rule will allow _____ months for the establishment of such a network. _____ months following the enactment of the rule, all RAMs will be required to be processed at Disposal Facilities prior to destruction or being put to an approved use.

The interim final rule will require prompt processing of RAMs by rendering, incineration or alkaline digestion. Research suggests these treatments will produce products free of pathogenic microorganisms. The interim final rule will require all Disposal Facilities to treat all waste materials from processing, including water, effluent, water vapor, ash and air contaminants to meet discharge and emission standards applicable to the process permitted under the Disposal Facility's license.

In addition, the interim final rule will require licensed facilities to collect data and maintain sufficient records to allow FDA and other federal and state agencies to trace RAMs back to their source and verify that materials from TSE-infected animals have been properly processed. The concentration of Dead Stock and non-ambulatory livestock, especially cattle, at licensed disposal facilities will facilitate disease surveillance efforts. FDA and State veterinarians will have greater access to "high risk" or "target-population" animals for the collection of tissue samples and pertinent information.

The interim final rule will also provide for the establishment of licensed Collection Centers, where RAMs from the surrounding area may be collected for transport to the Disposal Facility. They will also set forth procedures for collecting and handling RAMs before processing. The procedures are designed to ensure that such materials remain segregated from the food/feed supply and undergo prompt and sanitary processing by a licensed facility. To further ensure the safety of the food/feed supply, RAMs will be transported only in licensed vehicles operated by the Disposal Facility or its independent contractor from the source where generated and from the Collection Center to the Disposal Facility.

The interim final rule would permit the Commissioner or state regulator designees to inspect any Disposal Facility.

Legal Authority

Because the public health objective is to prevent the spread of communicable disease, we are issuing the rule under section 361 of the Public Health Service Act (PHS act) (42 U.S.C. 264). Section 361 of the PHS act authorizes the Secretary to make and enforce such regulations as judged necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or from one State to another State. We may regulate intrastate transactions under this authority as appropriate (see *State of Louisiana v. Mathews*, 427 F. Supp. 174 (E.D. La. 1977)).

We have invoked section 361 of the PHS act to regulate various activities and articles. FDA has invoked this authority, for example, to prevent the transmission of communicable disease through certain shellfish, turtles, certain birds, and human tissue intended for transplantation (see 21 CFR 1240.60 (molluscan shellfish), 1240.62 (turtles), 1240.65 (psittacine birds), and 1270.1

through 1270.43 (human tissue)). Similarly, the Centers for Disease Control and Prevention (CDC) have invoked section 361 of the PHS act to control the importation of dogs and cats, turtles, nonhuman primates, etiological agents, and dead bodies (see 42 CFR 71.51 through 71.55, respectively). CDC has also regulated the interstate shipment of etiologic agents under this authority (see 42 CFR part 72).

Section 368 of the PHS act (42 U.S.C. 271) provides the authority to enforce section 361 of the PHS act. Under section 368(a) of the PHS act, any person who violates a regulation prescribed under section 361 of the PHS act may be punished by imprisonment for up to 1 year (42 U.S.C. 271(a)). Individuals may also be punished for violating such a regulation by a fine of up to \$100,000 per violation if death has not resulted from the violation or up to \$250,000 per violation if death has resulted (18 U.S.C. 3559, 3571(b)). Organizations may be fined up to \$200,000 per violation not resulting in death and \$500,000 per violation resulting in death (18 U.S.C. 3559, 3571(c)). In addition, Federal district courts have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act.

We are proceeding without notice and comment rulemaking because we need to have regulations in place immediately to address the disposal and use of RAMs. Under the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(B), we find for good cause that prior notice and comment on this rule are impracticable and contrary to the public interest. It is imperative that we act quickly to implement these regulations to prevent the spread of communicable disease in the United States.

Analysis of Economic Impacts

Paperwork Reduction Act Analysis

Environmental Impact

List of Subjects

21 C.F.R. §§ 16.1 and 1240.70.

Under the authority of the Secretary of Health and Human Services delegated to the Commissioner in accordance with 21 C.F.R. section 5.10(a)(3), section 16.1 is amended and that section 1240.70 is inserted as part of Title 21 of the Code of Federal Regulations as follows:

21 CFR CHAPTER I

PART 16--REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

The authority citation for 21 CFR Part 16 continues to read as follows:

Authority: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

Section 16.1 is amended in paragraph (b)(2) by numerically adding an entry for Sec. 1240.70(w) to read as follows:

Sec. 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 1240.70, relating to refusal to issue or renew, suspension or revocation of disposal facility license.

* * * * *

PART 1240—CONTROL OF COMMUNICABLE DISEASES

The authority citation for 21 CFR part 1240 continues to read as follows:

Authority: 42 U.S.C. 216, 243, 264, 271.

Section 1240.70 is added to subpart D to read as follows:

DEDICATED DISPOSAL FACILITIES

Disposal Renderers

21 C.F.R. § 1240.70(a). Definitions.

Restricted Animal Materials (RAMs) means those animals or parts of animals that are prohibited for use in human food and/or animal feed supply, and include Dead Stock from which such prohibited material cannot be removed. Unless expressly included, however, muscle meat from Dead Stock or non-ambulatory cattle that is harvested for use in pet food is exempt.

Collection Center means a facility that collects materials for loading into a permitted vehicle for delivery to a Disposal Facility.

Dead Stock means cattle, sheep and goats [species to be defined by list of RAMs] that die or are killed other than by slaughter.

Disposal Facility means a facility for rendering and/or disposal of RAMs. The disposal can be by means of incineration or alkaline digestion by a Disposal Facility, state or federally permitted landfill following processing at a Disposal Facility, or any other means approved by the Commissioner, provided that such means is preceded by rendering at a Disposal Facility.

Rendering Facility means any facility which, for other than human consumption, collects, cooks, and processes carcasses or parts of carcasses of animals, poultry, or fish for the purpose of

salvaging hides, wool, skins, or feathers and for the production of animal, poultry, or fish protein, bone meal, grease, or tallow.

21 C.F.R. § 1240.70(b). Disposal Facilities.

(1) A Disposal Facility shall be licensed by the Commissioner. A list of licensees will be made publicly available and may be obtained from FDA. A license may be applied for or renewed by submission of a written application for or renewal of license form to FDA [address]. A license is in effect for one (1) year before renewal will be required. The original license shall be renewed for each subsequent calendar year during the December immediately preceding the subsequent calendar year upon payment of such license fees as determined by the Commissioner. All licenses not renewed during December of each calendar year shall expire on December 31 of that year.

(2) If a Disposal Facility employs an independent contractor to provide transportation of RAMs, the independent contractor shall secure a license through the licensed Disposal Facility to whom the RAMs will be delivered.

(3) Approval of a license or its subsequent renewal may be refused, suspended or revoked as provided in section 56.23. Such a license may be reinstated by the procedure in that section.

21 C.F.R. § 1240.70(c). Separation from Other Businesses.

Every licensed Disposal Facility shall be separate and distinct from any other facility, and from any establishment in which any food or feed destined for human or animal consumption is handled.

21 C.F.R. § 1240.70(d). Only Permitted Disposal Methods.

(1) Beginning ___ months after this rule becomes effective, RAMs shall be processed only in a Disposal Facility according to the provisions set forth in this section. If rendered material is to be disposed of, such disposal must be by approved methods as follows:

(A) Controlled incineration as specified in section 1240.70(h).

(B) Alkaline digestion as specified in section 1240.70(i).

(C) At a properly permitted (state or federal) landfill following rendering as specified in section 1240.70(g).

(D) Other disposal methods resulting in the total destruction of the material as approved by the Commissioner, provided that any such method is preceded by rendering at a Disposal Facility or provides comparable volume reduction, pathogen reduction and traceability as rendering and has been approved as an accepted method of disposal by the Commissioner.

(2) Material rendered at Disposal Facilities may also be used for non-food/non-feed industrial uses as permitted by section 1240.70(j).

(3) All approved Disposal Facilities must insure that all air, water and solid waste discharges generated by the rendering, incineration and digestion process shall be managed in accordance with the regulatory requirements applicable to rendering, incineration and digestion operations, respectively.

21 C.F.R. § 1240.70(e). Other Forms of Disposal Prohibited.

It shall be unlawful to dispose of unprocessed RAMs by burying, composting, open burning in a pyre, abandonment, or depositing in a landfill.

21 C.F.R. § 1240.70(f). Operations.

(1) Once delivered to a Disposal Facility, RAMs shall be rendered, incinerated or digested in alkali within 72 hours.

(2) Each Disposal Facility shall install real-time temperature and/or pH recording devices appropriate to the process and maintain records of those measurements, as well as calibration records as applicable.

(3) If necessary in the course of operations, Disposal Facilities may transport RAMs from one facility to another by the procedures specified in this Part for transportation of RAMs and associated recordkeeping.

(4) If after processing, RAMs are to be transported for use in non-feed applications or for disposal, the material must be labeled "NOT FOR HUMAN CONSUMPTION" and "NOT FOR ANIMAL CONSUMPTION".

(5) All operations of the Disposal Facility shall be in conformance with local municipal ordinances and State regulations.

21 C.F.R. § 1240.70(g). Rendering Procedures.

(1) A Rendering Disposal Facility shall use only methods of rendering that are sufficient to control conventional pathogens and improve the storability of the material. These shall include grinding all RAMs prior to processing and processing at a temperature at or exceeding 270° F (133° C).

(2) A Rendering Facility may be licensed for part-time operation as a Disposal Facility and used during the remainder of the time as a Rendering Facility. The Disposal Facility license will specify under what specific situation(s) the facility will operate as a Disposal Facility. Clean-out procedures for Disposal Facilities operating on a part-time basis ("Situational Disposal Facilities") shall be in conformance with section 1240.70(m).

21 C.F.R. § 1240.70(h). Incineration Procedures

An incineration Disposal Facility shall use only methods of incineration, including but not limited to incinerators, kilns, gasification technology and fluidized bed technology, which are sufficient to control conventional pathogens, reduce BSE infectivity and prevent the dissemination of pathogens to the air. Such control may be obtained by developing minimum process standards or end-point determinations

Particulate emissions discharged from Disposal Facilities must be further incinerated in an after-burner and conform to applicable local, state and federal permits.

21 C.F.R. § 1240.70(i). Digestion Procedures

A digestion Disposal Facility shall use only methods of chemical digestion sufficient to control conventional pathogens and inactivate the BSE agent. Process conditions will be specified by the Commissioner. Effluent discharges must meet all applicable waste water permits.

21 C.F.R. § 1240.70(j). Acceptable Uses for Processed RAMs

Rendered RAMs may be put to the following non-feed uses:

- (1) All tallow and grease derived from rendered RAMs may be used as fuel, fuel feedstock, non-cosmetic oleochemical products and lubricants.
- (2) Tallow containing a maximum of 0.15% insoluble impurities (protein-free tallow) may be used in animal feed or oleochemicals to be used to manufacture cosmetics.
- (3) Proteins derived from rendered RAMs may be used as fuel.
- (4) Ash from the incineration of RAMs may be land-applied according to applicable regulatory requirements, used as a component in industrial-grade construction materials, used in other applications as approved by the Commissioner, or disposed of in a state or federally permitted landfill.
- (5) Dried effluent from the digestion of RAMs may be land-applied according to local, state and federal permits.
- (6) Other uses as approved by the Commissioner.

21 C.F.R. § 1240.70(k). Records.

Each Disposal Facility shall maintain records sufficient to verify the disposal of an animal, group of animals, or parts of animals including:

- (1) A record which shall show as to all materials received:
 - (A) Name and address of person from which the materials were obtained

(B) Species of each animal or species of other RAMs until such time that a universal animal identification system is implemented which will make this information available in the animal identification database.

(C) Identification number on shipping container, can, or other receptacle and the time and date of the delivery of materials to the facility.

(2) A temperature and pH record including calibration records appropriate for the type of Disposal Facility.

(3) A record of the disposition of the final products of each disposal rendering operation, *e.g.*, method of destruction, date of delivery for end use, or details of use in a non-food/non-feed application.

These records may be maintained in any format, including electronically, provided they contain the information required above. All records shall be produced within two hours following the demand of the Commissioner or a State regulator for inspection and copying during normal business hours and shall be kept for a minimum of two years.

21 C.F.R. § 1240.70(l). Handling Materials.

(1) RAMs for destruction must be collected by haulers licensed to handle them. The RAMs may be delivered either directly to a Disposal Facility or to a Collection Center. A Collection Center will release RAMs only to a Disposal Facility or that facility's independent contractor for transport to a Disposal Facility.

(2) RAMs shall be removed from designated collection centers as rapidly as possible and shipped only to licensed Disposal Facilities.

(3) Dead Stock carcasses may be skinned and the hides may be used for non-feed purposes. If the hides are removed prior to delivery to a Disposal Facility, the carcass shall be sprayed with liquid charcoal to identify all parts of the carcass and preclude its use in animal feed. Hide trimmings and/or hide fleshings, other than protein-free hide fleshings, which are also derived from Dead Stock must be sent to a Disposal Facility.

(4) At the Collection Center, the physical segregation of RAMs from non-restricted animal materials must be maintained throughout the arrival and transfer to licensed transport vehicles. Some combination of physical barriers or cleaning procedures must be implemented to prevent the commingling of these two categories of materials.

(5) Collection Centers shall be operated so buildings used for the temporary storage of animal carcasses, packing house wastes, and other products before transportation to a licensed disposal facility are kept clean and in good repair and maintained so as to be susceptible of being thoroughly cleaned and protected from the entrance or harboring of vermin.

(6) Carcasses or packing house waste or containers of packing house waste unloaded at Collection Centers shall be unloaded in the holding building or on a slab of sufficient size to hold such material.

(7) The Collection Center shall maintain the following records:

(A) A record that shall show as to all materials received:

(i) Name and address of person from whom the materials were obtained and

(ii) Species of each animal or of other RAMs until such time that a universal animal identification system is implemented which will make this information available in the animal identification database.

(B) A record of the date said materials were retrieved from the Collection Center by a Disposal Facility, the identity of the Disposal Facility, and the address of the Disposal Facility to which said materials were sent.

(C) Identification number on shipping container, can, or other receptacle and the time and date of the delivery of materials to the Disposal Facility.

These records may be maintained in any format, including electronically, provided they contain the information required above. All records shall be produced within two hours following the demand of the Commissioner or a State regulator for inspection and copying during normal business hours and shall be kept for a minimum of two years.

21 C.F.R. § 1240.70(m). Clean-out Procedures for Situational Disposal Facilities

(1) Clean-out may be physical cleaning, flushing or other means either alone or in combination with separation measures, that are adequate to prevent carryover of RAMs into non-prohibited material. Clean-out procedures shall be used on all equipment, storage areas and conveyances.

(2) Documentation for clean-out shall describe cleanout procedures and implementation, indicate the party(ies) responsible, monitoring and verification procedures and the volume, justification and disposal of material used as flush.

21 C.F.R. § 1240.70(n). Denaturing.

(1) Except as specified in section 1240.70(1)(3), RAMs shall be denatured in accordance with the procedures set forth in 9 C.F.R. § 325.13.

(2) All denaturing shall be done immediately upon condemnation of the material.

Transportation

21 C.F.R. § 1240.70(o). Limitation on Transporting Dead Stock and Specified Risk Materials.

(1) No person shall transport any RAMs to any place except to a licensed disposal facility, a licensed Collection Center, or a federal, state or county diagnostic laboratory. No RAMs may be unloaded at any place ineligible to receive such materials; except that in case a vehicle is

disabled en route or in other extraordinary circumstances, the transporter of RAMs may unload the materials and reload them into an operable vehicle, *provided that* he shall immediately report the transfer and facts by email, facsimile, or telephone to the Compliance Staff, Center for Veterinary Medicine, 7519 Standish Place, HFV-1 Rockville, Maryland 20855.

(2) It shall be unlawful to load into any means of conveyance containing any RAMs bound for a Disposal Facility or Collection Center, any other products or other commodities.

21 C.F.R. § 1240.70(p). Licensed Vehicle Fleet or Independent Contractor.

(1) Each person operating a Disposal Facility shall maintain a licensed truck fleet for the collection of RAMs or shall employ an independent contractor who shall maintain such a fleet. Independent contractors contracting with a Disposal Facility shall be included on the license of that facility.

(2) Vehicles shall be equipped with leak-proof trailer bodies and boxes and shall be constructed so that the load is not visible.

(3) RAMs shall be transported only in licensed vehicles owned and operated by the Disposal Facility specified to receive the material or an independent contractor hired by the facility to transport the material to that facility.

(4) RAMs shall be transported directly from the Collection Center to the Disposal Facility.

21 C.F.R. § 1240.70(q). Cleaning and Sanitation of Vehicles.

(1) All vehicles used for the transportation of RAMs shall be thoroughly cleaned and disinfected at the end of each day's operation during which the vehicle or other means of conveyance was used. The cleaning process shall include the complete removal from the means of conveyance any fluid, parts or product of RAMs. Substances permitted for use as disinfectants include (i) Liquefied phenol (U.S.P. strength 87 percent phenol in proportion of at least six fluid ounces to one gallon of water), (ii) Cresylic Disinfectant (in the proportion of not less than four ounces to one gallon of water), (iii) Any other disinfectant approved by the Commissioner. Vehicles cleaned and sanitized in this manner may then be used for the transportation of other materials and products.

(2) Following the cleaning process and before reloading or leaving the facility, the vehicles will be inspected and determined to be free of any residual RAMs.

(3) A written record will be kept documenting the cleaning and inspection process that includes the date and time of the cleaning and inspection, the inspector's name, the outcome of the inspection, and any corrective actions taken.

21 C.F.R. § 1240.70(r). Vehicle Cleaning Area.

(1) Each Disposal Facility shall maintain a vehicle cleaning area.

(2) The vehicle cleaning and sanitizing area shall be maintained and operated so that the waste from such operation is disposed in a manner as to prevent a nuisance or human or animal health hazard.

21 C.F.R. § 1240.70(s). Shipping Containers, Cans and Other Receptacles.

(1) Shipping containers, watertight cans and other receptacles used for holding materials being transported to the Disposal Facility shall be so constructed as to be readily cleaned, and they are to be cleaned and sanitized after each use. Cans and other receptacles found to be uncleaned and unsanitized after each use or in such state of disrepair that they cannot be readily cleaned and sanitized or which are not watertight shall be tagged "reject" by any Federal or State inspector when found in such condition. Such tagged receptacles shall not be used again until they are brought into compliance and the reject tag is removed by a Federal or State inspector.

(2) All containers, cans and other receptacles used for holding materials shall be marked conspicuously with the words "NOT TO BE USED FOR HUMAN FOOD," or "NOT TO BE USED FOR ANIMAL FEED," or a combination, as applicable to the particular RAMs in letters not less than 2 inches high. All shipping containers shall be painted with a durable paint, if necessary, to provide a contrasting background for the required marking.

(3) The identification number shall also appear on the bill of lading or other transportation document for the shipment.

21 C.F.R. § 1240.70(i). Records.

(1) Each person who transports in commerce RAMs to a Disposal Facility shall keep records which shall show as to all RAMs:

(A) Date and time of pick up.

(B) Name and address of person from which the materials were obtained.

(C) Species of each animal or of other RAMs until such time that a universal animal identification system is implemented which will make this information available in the animal identification database.

(D) Identification number on shipping container, can, or other receptacle, if applicable.

(E) Time and date of delivery to Disposal Facility.

These records may be maintained in any format, including electronically, provided they contain the information required above.

(2) Each person who transports in commerce RAMs shall retain original copies of bills of lading or other transportation documents, including the identification number from each shipping container delivered to the Disposal Facility.

All records shall be produced within two hours following the demand of the Commissioner or a State regulator for inspection and copying during normal business hours and shall be kept for a minimum of two years.

Inspection; Penalties; Withdrawal of Approval

21 C.F.R. § 1240.70(u). Inspection

Each Disposal Facility and Collection Center licensed under this part is subject to inspection by the Commissioner or his representative each year, or as often as the Commissioner deems necessary, to determine compliance with the requirements set forth in this part. The Commissioner may appoint state regulators to conduct the inspections.

21 C.F.R. § 1240.70(v) Penalties

Any person who violates this regulation or any rule, regulation or order of FDA issued pursuant to this regulation may, after notice and an opportunity for a hearing on the record, be assessed a civil penalty by the Commissioner that does not exceed the greater of:

- (1)(i) \$50,000 in the case of any individual or entity involved in the operation of a Disposal Facility, Collection Center or in the transportation of RAMs, as defined in this regulation, except that in the case of an initial violation of this regulation, the civil penalty assessed shall not be less than \$5000 unless the initial violation is by an individual operating not for pecuniary gain, in which case the maximum fine will be \$1000; and
- (ii) \$500,000 for all violations adjudicated in a single proceeding; or
- (2) twice the gross gain or gross loss for any violation under this regulation that results in the person's deriving pecuniary gain or causing pecuniary loss to another person
- (3) Each day of violation shall constitute a separate offense under this regulation.

21 C.F.R. § 1240.70(w). Refusal To Issue or Renew, Suspension or Revocation of License.

(1) The Commissioner may refuse to issue or renew or may suspend or revoke a license to operate a Disposal Facility, including to transport RAMs through a facility's own vehicles or through an independent contractor, on the grounds, including but not limited to any one or more of the following:

- (A) The making of a material misstatement of fact in the application for an original license or in the application for any subsequent renewal of the license;
- (B) Willful disregard or willful violation of this regulation or any rules or regulations issued pursuant thereto;
- (C) Willful aiding or abetting another in violation of these regulations or any rules or regulations issued pursuant to thereto;

(D) A licensee allowing its license to be used by an unlicensed person or entity;

(E) Conviction of a crime, an essential element of which is the material misstatement of fact, fraud or dishonesty, or conviction of a crime relative to the disposition of RAMs or the provisions of these regulations, if after investigation, a determination is made by the Commissioner that such person or entity has not been sufficiently rehabilitated to warrant the public trust;

(F) Making material misrepresentations or false promises of a character likely to influence, persuade or induce in connection with the business of a licensee;

(G) Pursuing a continued course of willful misrepresentation or making false promises through advertising, salesmen, agents, or otherwise in connection with the business of a licensee; or

(H) Failure to possess the necessary qualifications to meet the requirements of these regulations for the issuance or holding a license.

(2) The Commissioner may, upon his or her own motion, and shall, upon the verified written complaint of any person setting forth facts which, if proved would constitute grounds for refusal, suspension or revocation of a license, investigate the actions of any applicant or person, persons, entity or entities, holding or claiming to hold a license. Before refusal to issue or renew, and before suspending or revoking a license, the Commissioner shall, in writing, notify the applicant or licensee of the opportunity for a hearing in accordance with part 16 of 21 CFR.

(3) A suspended license may be reinstated through a showing, acceptable to the Commissioner, that the issues leading to the suspension of the license have been corrected and that the licensee is in full compliance with the regulations.