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December 20, 2005

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

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

Dear Sir/Madam:

Darling International Inc. ("Darling") references The Food and Drug Administration's (FDA) Docket No. 2002N-0273, the agency's proposed rule and the invitation to comment on substances prohibited from use in animal food or feed.

Darling is one of America's leading providers of rendering, recycling and recovery solutions to the nation's food industry. With processing facilities located in 14 states, Darling is one of the largest independent rendering companies and the only publicly traded independent rendering company in the United States (US).

Darling is a member of the National Renderers Association (NRA), American Protein Producers Industry (APPI), Fats and Proteins Research Foundation (FPRF) and the American Feed Industry Association (AFIA). We are aware of comments submitted to Docket No. 2002N-0273 by each of these organizations and generally support their comments.

Notwithstanding the forgoing, Darling disagrees with the amendments to 21 C.F.R. § 589.2000 ("Feed Rule") and the new 21 C.F.R. § 589.2001 proposed by the FDA, for the following reasons:

1. The risk of spreading bovine spongiform encephalopathy (BSE) is extremely low, based on surveillance data from the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) indicating that one case of BSE was detected out of 548,786 samples taken for the period June 1, 2004 through December 11, 2005.

02N-0273

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2. Failure of the FDA and/or other federal agencies to simultaneously address the disposal of materials [brain and spinal cord (“B/SC”) from cattle over 30 months of age, B/SC from all cattle not inspected and passed for human consumption (“Dead and Downer Cattle”) and Dead and Downer Cattle from which B/SC cannot be removed], that are proposed to be banned from feed, threatens animal health because improper disposal of such materials will increase animal exposure to conventional pathogens that were previously controlled by rendering.
3. Proposed changes to the Feed Rule were developed by the agency using flawed or incomplete data about rendering industry practices, volumes and capabilities.

Darling participated with many other rendering companies in a survey developed, analyzed and summarized by Informa Economics (“Informa”)¹. Virtually all rendering companies within the industry were surveyed. The NRA submitted, with their own comments, the complete Informa study to the docket, which we incorporate into our comments by reference. Darling believes these data and the conclusions drawn by Informa provide essential information about the rendering industry that the FDA should carefully review before attempting to finalize the proposed rule. The Informa report concluded that rendering is used for the disposal of approximately 45% of all dead cattle and calves in the United States, which reflects the importance of rendering as a disposal option for dairy and beef producers. The Inform data is in stark disagreement with the Eastern Research Group (ERG) study², which estimated that only 17% of dead cattle in this country were rendered. Informa also surveyed rendering practices and predicted the impact of the proposed regulations on rendering industry practices and the cost of compliance if those regulatory changes become effective. Darling urges the FDA to conduct more extensive economic and environmental impact studies in light of this new information. In addition, the FDA and other appropriate federal agencies are urged to conduct a thorough joint assessment to determine the potential risk to livestock, poultry and humans from conventional pathogens if materials that have been disposed of through rendering in the past are no longer rendered and are thus disposed of by other methods, especially low cost methods such as abandonment. Failure to perform a thorough due diligence before a final rule is promulgated will result in unintended consequences that could negatively impact the livestock, poultry, dairy and meats industries, animal and human health, and the environment.

Darling is aware that the FDA has been pressured to develop additional BSE safeguards since two cases of BSE were reported in the domestic cattle herd. We also appreciate the importance of regaining export markets for beef and beef products lost because of BSE and the lack of uniform BSE safeguards for North America. Darling supports science-based rulemaking to address animal health issues. Based on results of the enhanced BSE surveillance program administered by APHIS, however, BSE is not an animal health issue in the United States and additional safeguards, such as those proposed, are not necessary to further protect animal health. If the proposed rulemaking does not address an animal health issue, then the driving force must be to regain lost export markets. Such rulemaking is not in the best interest of science and risk management and sets a precedent to use the “precautionary principle” whenever political or market driven issues that do not have clear animal or public health implications arise. The low incidence of BSE combined

¹ Informa Economics, *Economic Impacts of Proposed Changes to Livestock Feed Regulations*, December 2005.

² Eastern Research Group, Inc., *Economic Impacts of Proposed FDA Regulatory Changes to Regulation of Animal Feeds Due to Risk of Bovine Spongiform Encephalopathy*. July 25, 2005.

with the use of flawed or inaccurate data about the rendering industry by the FDA in developing the proposed additional restrictions for animal food and feed places an unreasonable burden on the rendering, livestock, and dairy industries and potentially places small commercial slaughter operators at a competitive disadvantage.

FDA has grossly misstated the impact of B/SC removal from Dead and Downer Cattle

We believe that the FDA has overestimated the rendering industry's ability to remove B/SC from Dead and Downer Cattle. B/SC removal from cattle carcasses is not commonly done in the rendering industry and few rendering companies have the facilities, equipment or expertise to easily adopt such practices. Darling agrees with the Informa estimates that only about 54% of Dead and Downer Cattle carcasses are in good enough condition to allow removal of the B/SC to be attempted³. Decomposition will be too advanced in the remaining carcasses. The Informa estimate was, however, for a typical year. A number of factors affect the rate at which a carcass decomposes; including time lapsed between death of the animal and processing, ambient temperature, and age and specie of animal. Seasonal and regional conditions will significantly influence the number of carcasses in good condition that are presented to a rendering facility on any given day. During late spring, summer and early fall, as few as 10% of all cattle carcasses may be fresh enough for B/SC tissues to be successfully removed in the southern, southeastern and southwestern parts of the United States. B/SC removal may be feasible in a higher percentage of carcasses for a greater portion of the year in the northern parts of the country, provided rendering companies are able to add the necessary facilities, equipment, labor and procedures.

Despite comments in the proposed rule to the contrary⁴, the methods used to handle cattle carcasses in rendering plants differ considerably from methods used in the beef slaughter industry. Carcasses are seldom placed on rails before rendering or, if rails are used, they are used only to facilitate hide removal and are not of sufficient height or design to accommodate the splitting of the carcass and removal of spinal cord material. We urge the FDA to tour at least one typical rendering plant that routinely handles Dead and Downer Cattle in order to better understand the issues and the challenges created by the proposed removal of B/SC material.

To comply with the proposed rule, many rendering companies will find it necessary to make substantial capital investments to modify existing facilities, install refrigeration equipment or freezers, modify both collection routes and procedures to obtain fresher carcasses, and develop methods to remove B/SC material from Dead and Downer Cattle carcasses if they chose to continue handling such carcasses. As a result, costs associated with the collection and processing of dead cattle will increase markedly, as would the fees charged to farmers and ranchers for such services. Informa⁵ reported that among rendering facilities that would continue to handle Dead and Downer Cattle if the proposed rule is finalized, service fees are likely to increase 200% to 600% for the collection of dead cattle over 30 months of age, feedlot cattle, and other cattle less than 30 months of age. Collection fees for calves will be impacted the most. Approximately 55% of rendering facilities that currently handle dead calves do not plan to remove B/SC from them and

³ Informa Economics, *Economic Impacts of Proposed Changes to Livestock Feed Regulations*, December 2005. Pages 12 – 13.

⁴ Federal Register, *Substances Prohibited From Use in Animal Food or Feed*, October 6, 2005. Vol. 70, No. 193, page 58575.

⁵ Informa Economics, *Economic Impacts of Proposed Changes to Livestock Feed Regulations*, December 2005. Pages 12-14.

will discontinue calf carcass collections. Calf carcasses have low finished product yields because of their small size and high water content, which makes it difficult for renderers to recover any additional costs associated with B/SC removal.

In some instances, renderers may choose to develop a dual charging program for all cattle carcass collections, with one fee for carcasses that are fresh enough for the B/SC to be removed and a higher charge if the carcass is too decomposed for the B/SC to be removed, requiring disposal by other means. In each case, the collection fees will be higher than current charges and require that renderers make significant changes in accounting and invoicing policies and procedures. Many livestock producers are expected to refuse to pay higher prices for dead animal disposal and to seek alternative methods that are cheaper. Because dead animal disposal is poorly regulated, the cheapest options, such as abandonment and burial, will become the methods of choice in the absence of uniform disposal standards that are enforced and a plan to help producers with the disposal costs.

We are aware of commercial methods developed for use on the kill floor of slaughter facilities to remove the brain from intact skulls and to remove the spinal cord from the vertebral column after beef carcasses have been split. Such procedures may, however, be suitable only to support claims made by those slaughter establishments that finished rendered products are B/SC-free in order to gain a marketing advantage or receive a premium. Verification that the entire brain has been removed, to assure regulatory compliance, would require that each skull be split and visually evaluated (in the absence of approved analytical testing methods) for the presence of residual brain tissue. In addition, while most of the spinal cord may be removed, some residual tissue may remain attached to the vertebral column of carcasses. We further understand that as the animal ages, nervous tissue from the spinal column becomes more involved with bones in the vertebral column, making complete spinal cord removal more difficult. As explained above, this problem is compounded by the effects of decomposition. We thus do not believe that this method is feasible for B/SC removal from Dead and Downer Cattle in a typical rendering plant.

We do not have first-hand knowledge of other methods that might be used. Removal and disposal of the entire head is certainly one possibility. Such a practice will, however, markedly increase the volume of material that must be disposed of from less than one pound to 16 pounds⁶ or more per carcass. Methods for removing spinal cord from an un-split carcass might be feasible, provided the spine is not broken or damaged from loading, unloading and handling of the carcass. We are also not aware of any methods to verify complete spinal cord removal from carcasses that have not been split.

B/SC residues have not been an issue in the past, even with the required SRM removal from human food, because neither tissue is considered SRM in slaughter cattle less than 30 months of age and the removal of other tissues that either contain or include B/SC is required from cattle over 30 months of age. USDA and FDA both consider the skull, including the brain, and the vertebral column, which includes the spinal cord as well as the trigeminal ganglia, to be SRM for older cattle. Because rendering B/SC from all cattle carcasses to make meat and bone meal for nonruminant feed has previously been allowed, the need to verify that either the brain or the spinal cord have been or can be removed has not existed in the past, other than to support certain

⁶ Eastern Research Group, Inc., *Economic Impacts of Proposed FDA Regulatory Changes to Regulation of Animal Feeds Due to Risk of Bovine Spongiform Encephalopathy*. July 25, 2005. Page 2-3.

marketing claims by individual companies. Given the apparent difficulty in assuring complete B/SC removal in hanging carcasses as well as whole dead cattle, as discussed above, the FDA must provide guidance as to how the agency will evaluate efforts to remove these materials from the skull and vertebral column in slaughter plants and from the carcasses of Dead and Downer Cattle. Such criteria are important for industry to be able to critically evaluate new and existing removal methods for cost, efficacy and the potential to leave B/SC tissue residues on material destined for rendering which, in agency's opinion, might constitute non-compliance and result in enforcement action taken against the facility. Such cost/risk analyses may influence the decision of slaughter facility operators and renderers to accept or reject certain types of material, which in turn, will influence the volume of material that can be rendered or must be disposed of by other means.

In the proposed rule, the FDA indicated concern that, unlike most slaughter facilities, federal inspectors are not typically present at rendering plants to verify the age of carcasses. The agency cited this concern in its decision to propose that B/SC be removed from all cattle not inspected and passed for human consumption. We are not aware of any analytical procedures to test for B/SC in carcasses of any age. Therefore, verification that such materials were removed from all dead cattle will be based on documentation, making the agency's argument against allowing Dead and Downer cattle less than 30 months of age to be rendered without removing the B/SC illogical. The proposed rule indicates that renderers will be required to "establish and maintain records sufficient to track the prohibited materials to ensure such material is not introduced into animal feed...".⁷ Even though the proposed rule does not specify the extent and type of records required for inspectors objectively to determine compliance, the rule is still records-based. Therefore, it would seem logical to allow renderers to document that age was verified and only carcasses of cattle less than 30 months of age were rendered for use in animal feed.

Darling agrees with comments from our trade associations (NRA and AFIA) indicating that it is unnecessary to require the removal of B/SC from Dead and Downer Cattle less than 30 months of age, provided age can be verified based on criteria the agency establishes. Such criteria could include farm or ranch records, dentition, and identification in an established animal identification database that is recognized by USDA or appropriate state government agencies. Allowing cattle less than 30 months of age to be rendered without removing B/SC is consistent with the science as applied to cattle that are inspected and passed for human consumption.

Renderers are the "gatekeepers" for enforcement.

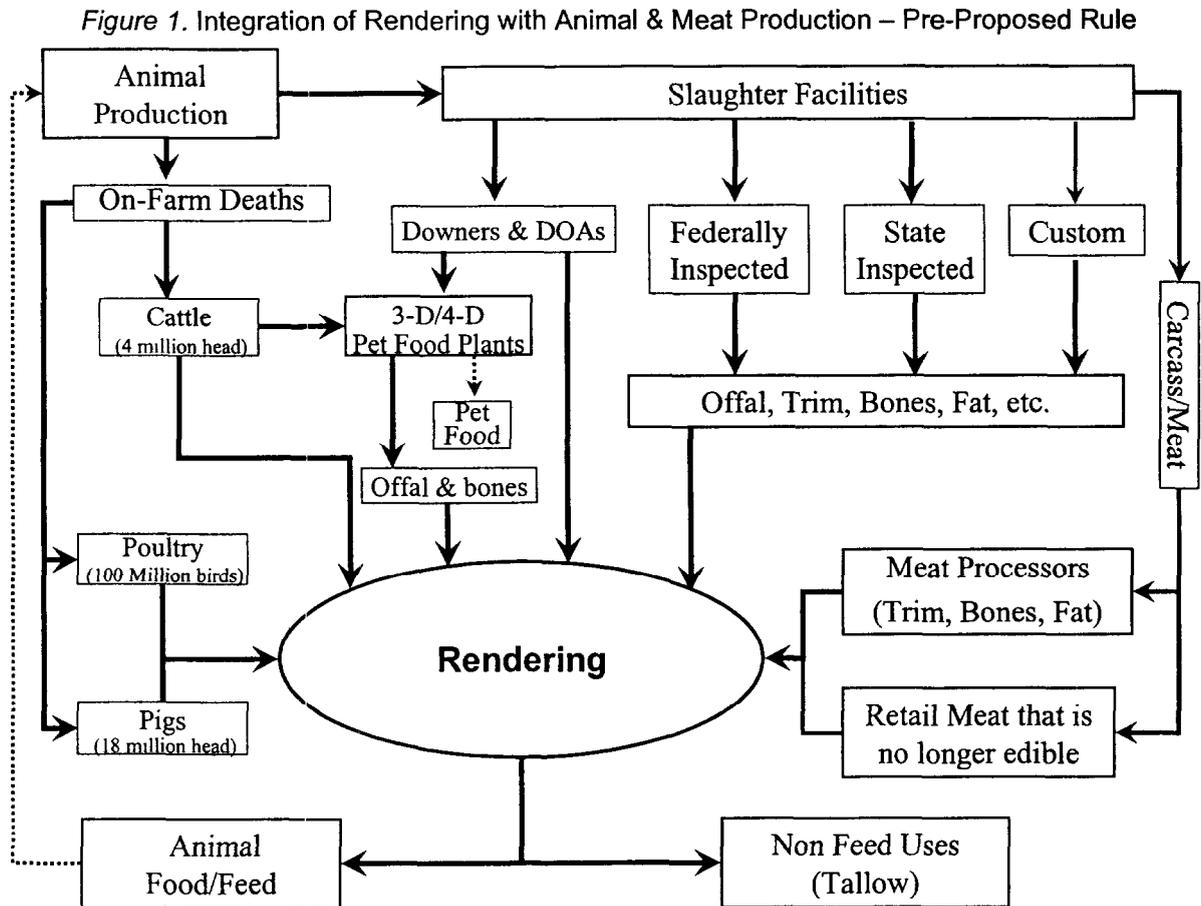
It is clear from the proposed rule that renderers will be the focus of enforcement activities. The requirements for labeling and marking prohibited materials are reasonable, although we encourage the agency to consider employee safety and ease of use in approving visual markers.

The proposed rule indicates that renderers will be required to "establish and maintain records sufficient to track the prohibited materials to ensure such material is not introduced into animal feed...".⁸ We urge the agency to examine closely the extent to which rendering is integrated with the animal production and meat processing industries as the agency considers the types of

⁷ Federal Register, *Substances Prohibited From Use in Animal Food or Feed*, October 6, 2005. Vol. 70, No. 193, page 58581

⁸ Id.

certifications, records and documentation needed for a facility to verify compliance during an inspection. Figure 1 illustrates the many sources of animal mortalities and animal byproducts for rendering. We are especially concerned with how the interpretation of this requirement will impact small slaughter, meat processing (custom slaughterers and meat lockers), 3-D and 4-D processing plants that do not have federal inspectors on-site. While some of these small businesses operate under state inspection, inspectors are not required to be present during slaughter in all states. In these cases, the facility is inspected rather than the day-to-day slaughter and/or meat processing procedures. Therefore, it is important that small businesses such as these are able to provide certification that the prohibited materials were removed at slaughter and not sent for rendering. Without such provisions, the proposed rule will place small businesses at an unreasonable competitive disadvantage. In some cases, small slaughterers may be forced to refuse cattle that are over 30 months of age, which will remove a viable salvage market for cull cattle and disadvantage dairy and beef producers.



Because the B/SC from cattle less than 30 months of age cannot be distinguished from B/SC taken from cattle over 30 months of age, written records are the only enforcement tool available to inspectors. The agency will need to develop objective methods for reviewing records of compliance and insure that all FDA and contract inspectors are well trained in such procedures. We are very concerned that without adequate forethought regarding inspection criteria and thorough training, inspectors will subjectively evaluate records, resulting in inconsistent and variable application of the requirements.

Darling is committed to complying with all applicable regulations. When faced with the potential for subjective interpretation of rules and regulations, we will choose (and have previously chosen) to err on the side of caution when determining and managing potential risks to the company. Other rendering companies apparently share these concerns. Informa⁹ acknowledged general concern about potential liability related to handling B/SC material from cattle over 30 months of age because the possibility exists that such proposed prohibited materials may intentionally or unintentionally be commingled at the slaughter facility with material from younger cattle. The burden of proof that such an act did not occur will fall on the renderer. Because the B/SC from older cattle can not be distinguished from B/SC removed from younger cattle, the renderer may be required to initiate an expensive product recall. Informa reported a strong reluctance, among renderers who participated in the survey, to continue collecting any material from non-federally inspected meatpacking plants or facilities because of these potential risks¹⁰. Darling may also be compelled to discontinue collection services for facilities that do not have a federal inspector present to verify that the proposed prohibited materials were removed and segregated, unless the FDA will accept written certifications of compliance from the slaughter/processing facility and hold the renderer harmless. Absent guidance from the agency on this matter, non-federally inspected slaughter/processing facilities will be forced either to arrange for acceptable alternative disposal or to close. Certainly, there is precedent for just such outcomes when rendering services had to be discontinued.

The proposed rule also potentially affects the collection and transport of dead animals of non-ruminant species, such as pigs and horses. Typically, trucks are dispatched on predetermined routes to collect dead animals, based on call-ins and prearranged or scheduled service-calls. As the volume of material and/or number of accounts on a given route decrease, the cost per unit must increase to recover the costs associated with running the route. It is not always feasible simply to combine routes or expand an existing route due to distance and time limitations on drivers and impact on raw material quality (i.e., hides, B/SC removal, tallow quality, etc.). Therefore, the cost either per stop or per animal collected must increase. If the increase is too great, customers drop out, causing a further increase in cost, resulting in a self-perpetuating cycle until the collection service is discontinued. This has already happened in some of our service areas. In many instances, the volume of cattle carcasses underwrites the collection of other species on a route. If the volume collected from one area becomes too small and unprofitable, all services may be discontinued, creating problems for small slaughter facilities, meat processors and in some instances retail stores. Some of these facilities may turn to alternative disposal means, such as burying or landfilling untreated materials. As discussed below, these unprocessed materials potentially create a reservoir for the spread of zoonotic disease. Other facilities, as explained above, would be forced to close.

In addition to processing animal byproducts and mortalities, rendering facilities and the associated network of transfer stations and independent "dead stock peddlers" provide for the biosecure collection of dead animals from farms, feedlots, dairies and slaughter plants for transport to rendering facilities. In most states, such materials can only be transported in leak-proof vessels by licensed renderers or their designated agents. If dead cattle are not rendered, and such collection

⁹ Informa Economics, *Economic Impacts of Proposed Changes to Livestock Feed Regulations*, December 2005. Page 21.

¹⁰ Informa Economics, *Economic Impacts of Proposed Changes to Livestock Feed Regulations*, December 2005. Pages 27-28.

and transport is left to individuals that lack experience and proper equipment, then an important control to prevent the spread of disease will be lost.

A USDA-Led Federal task force is needed to develop a disposal plan.

Carcass disposal is one of the most important issues created by the current draft of this proposed rule and has broad animal health, human health and environmental protection implications. Because the FDA grossly underestimated the impact their proposed regulations will have on the rendering industry, a number of trade associations and the United States Animal Health Association (USAHA) have expressed concern over this unintended consequence. USAHA passed a resolution at its 2005 annual meetings in Hershey, PA stating that: "*The United States Animal Health Association (USAHA) urges the Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), to more thoroughly evaluate the unintended consequences of changes in the Ruminant Feed Rule so that reducing a very small risk from Bovine Spongiform Encephalopathy (BSE) does not lead to a carcass disposal crisis in many areas of the United States*"¹¹. Darling agrees with the concerns expressed by the USAHA. Unless carcass disposal is addressed, the further reduction in the small risk of BSE which this proposed rule provides may result in a much greater threat to human and animal health from diseases caused by conventional pathogens that were previously kept under control by rendering. Therefore we encourage federal agencies to address the disposal issue by forming a task force with USDA in the lead. We are aware that USDA and the Environment Protection Agency (EPA) have been studying carcass and specified risk material (SRM) disposal for some time, with some involvement from FDA and the Department of Homeland Security. USDA has broad authority regarding animal health issues and published an ANPR on animal mortality disposal in 2003¹². It should be the lead agency in addressing this issue. A model rule for regulating the disposal of animal materials that are banned from feed is attached (Appendix A), which agencies may use as a roadmap when addressing this issue.

Need to ban additional tissues?

We agree with the FDA's assessment that the proposed rule will have a lesser impact on disposal than prohibiting the complete list of SRM (tonsils and distal ileum of all cattle and brain, skull, eyes, trigeminal ganglia, spinal cord, and dorsal root ganglia from cattle over 30 months of age) required for meat and meat products intended for human consumption. We do not believe such a complete prohibition is warranted given both the low incidence of BSE in the US and the failure of federal government agencies to develop a concomitant plan to insure that prohibited materials are disposed of appropriately.

Comments about the oral infectious dose.

The study suggesting the oral infectious dose to be 10 mg or less of BSE infected material is still in progress and, to our knowledge, has not been published in a peer reviewed scientific journal. The agency has used this preliminary data to partially justify taking additional measures to prevent the spread of BSE and to question the potential for cross-contamination of feed intended for

¹¹ 2005 USAHA Meeting Resolution #2 <http://www.usaha.org/committees/resolutions/2005/resolution02-2005.pdf>

¹² Federal Register, *Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species*, January 21, 2003. Vol. 68, No. 13 Pages 2703-2711.

ruminant animals with feed intended for non-ruminant animals. If, in fact, the infectious dose is 10 mg or less, we do not understand why the agency is concerned with feed cross-contamination issues without also being concerned with how B/SC, carcasses and other proposed prohibited materials are disposed of.

It has been widely assumed that BSE is spread by oral transmission. The consumption of contaminated feed is only one route of oral transmission. Cattle are non-selective eaters and will chew or mouth almost any object and use their tongues to gather forage into their mouths. The indiscriminate disposal of carcasses or tissues infected with the BSE agent can contaminate pastures, water and other materials in the environment and lead to oral exposure and disease transmission, in the same manner as infected feed.

Maximum impurity level for tallow used in feed.

The FDA is asked to clarify their proposal to limit the level of insoluble impurities in tallow intended for feed to 0.15% or less. The proposed rule is unclear as to whether such a requirement would apply to all tallow used for animal feed or only to tallow derived from materials that are proposed to be prohibited from animal food and feed.

Most Darling facilities were modified to insure that they could produce tallow meeting this standard when the FDA required that tallow used for food and cosmetics contain less than 0.15% insoluble impurities in 2004. Additional processing steps are sometimes necessary to insure that the impurity levels do not exceed this level, however, which adds to the processing costs.

To our knowledge, the BSE agent is associated with protein and has not been shown to be associated with tallow. The insoluble impurities in tallow typically include small particles of dirt and other foreign material. The small amounts of protein that may or may not be present are typically from hair, bone and other tissues having little to no innervation. The extremely low incidence of BSE in the US, the limited relative volumes of SRM and the unlikely presence of innervated protein tissues that may be present as impurities make it extremely unlikely that the BSE agent can be transmitted with tallow.

In the US, tallow is sold according to trading rules established by the American Fats and Oils Association (AFOA), which include limits on moisture, insoluble impurities and unsaponifiables (MIU). Moisture is typically the largest component of MIU.

Regulatory limits on the percent of insoluble impurities in tallow are not necessary and do little to protect against the spread of BSE. If the agency feels compelled to finalize the tallow provisions of the proposed rule, we suggest restricting any such limit only to tallow derived from prohibited materials. We encourage the agency to study the economic impact such action will have on industry before finalizing this portion of the rule

Despite our position that limits on impurity levels of tallow used for feed are unnecessary, Darling applauds the FDA's decision to adopt the AOCS method for determining impurity levels in feed.

Blood and blood products

To our knowledge, blood has never been identified as an SRM and has not been shown to concentrate or transmit the BSE agent. Therefore, there is no scientific basis to prohibit the use of blood or blood products in feed intended for ruminant or non-ruminant animals. We appreciate the fact that the presence of some bovine proteins, such as blood and blood products, in feed for ruminant animals makes it impossible to use DNA testing to determine compliance to the Feed Rule. However, blood and blood products are important feed ingredients for ruminant animals, especially young animals, and it is not logical to prohibit their use without strong scientific evidence that BSE can be spread by the feeding of such ingredients.

Plate waste

The only reason to ban plate waste is to facilitate testing of materials for ruminant tissue. Plate waste consists of meat that has been inspected and passed for human consumption. As required by FSIS and FDA, the full list of SRM was removed from such meat at slaughter and did not enter the human food chain as such. While some rendering facilities collect, process and market grease used in restaurants to fry foods, such facilities seldom collect and process plate waste. Plate waste is handled by a separate industry which collects the material for processing for use in animal feed.

Disposal Rendering

The United Kingdom recognized the importance of rendering or other technologies that utilize high temperatures or chemical treatment to kill bacteria, viruses and other conventional pathogens that are common in unprocessed animal byproducts and mortalities¹³. The rendering industry in the United States has established a proven infrastructure for handling such materials and is an important component of many state animal health programs, including disaster management plans. It is therefore logical that rendering would be considered to play a critical role in the collection, transportation, processing and disposal of all animal byproducts and mortalities, whether or not such materials are permitted to be used to produce ingredients for animal food or feed.

As explained in previous sections of these comments and described by Informa¹⁴, capital costs of \$2 to \$3 million are necessary to modify and/or expand existing rendering facilities in order to allow for segregated processing of prohibited materials. In addition, annual operating costs were expected to average just over \$1 million per year to process an average of only about 500,000 pounds of material per week¹⁵, which is about the volume of material one average size rendering facility might process in one day. About one year of construction/installation time would be required to modify an existing facility to add a dedicated processing line. It would also take three months to one year to secure the necessary permits for such installation. In some states, permits can only be obtained for replacement equipment and may not be available for any form of perceived expansion, especially if the agencies and/or boards associate a separate processing line with any increase in processing volume or capacity.

¹³ United Kingdom Department of Health, *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/>.

¹⁴ Informa Economics, *Economic Impacts of Proposed Changes to Livestock Feed Regulations*, December 2005. Pages 25 – 27.

¹⁵ Id.

The FDA assumed that with publication of the proposed rule, existing rendering facilities will either be dedicated to processing the proposed prohibited materials or expanded to add separate processing lines to handle such materials. Even if traditional markets for tallow, derived from prohibited materials and containing less than 0.15% insoluble impurities, can be maintained, the solid residue remaining after rendering (such as meat and bone meal) will have a negative market value. Disposal renderers will be forced to recover a substantial amount of their operating costs, plus margin, from service charges. As discussed previously, most livestock producers will be unwilling to pay these higher costs.

In order for disposal rendering to develop as a viable industry and, thus, a practical disposal option, uniform disposal requirements must be developed first. A system for assisting livestock producers with the costs of disposing of their dead cattle will also be needed. Without such a disposal plan in place before the proposed rule is finalized, disposal rendering will not be sustainable. A model regulation that can be used as a roadmap by federal agencies to develop a disposal plan is attached as Appendix A to these comments.

Conclusions.

Darling supports science-based rulemaking, but disagrees with the proposed amendments to C.F.R. § 589.2000 and the new 21 C.F.R. § 589.2001 because the risk of BSE in the United States has been shown to be extremely small, the FDA and other federal agencies failed to consider the disposal of the materials proposed to be excluded from feed and the FDA based development of the proposed rule on inaccurate data regarding the importance of the rendering industry for the disposal of dead cattle, non-ambulatory cattle and slaughter byproducts derived from cattle. An industry-commissioned study indicates that approximately 45% of cattle and calves that die in the United States each year are rendered. This new data supports previous studies, which were largely ignored by the agency in favor of limited data obtained from a single personal communication. As a result, the FDA has not adequately considered the unintended consequences of the proposed rule on carcass disposal issues or on the rendering, livestock and meats industries.

Darling strongly recommends that the FDA conduct in-depth economic and environmental impact studies that use the new data provided by Informa Economics. We also urge the FDA to encourage development of a federal task force, led by USDA to more closely examine disposal issues created by the proposed rule and develop appropriate uniform federal regulations for the safe disposal of materials that might be prohibited from feed in the future. To offset the costs associated with disposal, the task force should also facilitate research into new uses for animal based materials that are of little to no value once removed from feed. We hope the agency will delay finalizing the proposed rule until after the disposal issues and other unintended consequences associated with the proposed rule, as currently drafted have been adequately addressed.

Darling International Inc. Comments to Docket No. 2002N-0273

We are available to discuss these comments and/or host a tour of one or more rendering facilities where dead and non-ambulatory cattle are routinely processed, both at your convenience

Sincerely,

A handwritten signature in black ink, appearing to read "C. Ross Hamilton". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

C. Ross Hamilton, Ph. D.
Director Government Affairs and Technology

Enc.: Appendix A

Cc: Tom Cook, President
National Renderers Association

Appendix A

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 C.F.R. Part 56

Proposed Regulations; Foreclosure of Potential BSE Pathways Involving Animal Materials Restricted From the Human Food and/or Animal Feed Chain

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim Final Rule

SUMMARY: The Animal and Plant Health Inspection Service (APHIS) 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) and other Transmissible Spongiform Encephalopathies (TSE) 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, 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 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. In order to facilitate the separate disposal of RAMs and to reduce the disease-transmission potential of such materials, the interim final rules requires that RAMs be destroyed or diverted to acceptable non-food/non-feed uses by federally licensed operators. By requiring that those materials with the highest potential for infection be segregated from the general feed supply before processing and that such materials be disposed of using approved methods or put to specific, approved, non-food/non-feed uses, the interim final rule will address the issues raised in the earlier Notice.

APHIS has primary authority for animal disease risks from both live and dead animals on the farm, including animal health risks posed by the disposal of animal carcasses.¹ RAMs are considered an important potential pathway for the spread of BSE. Proper disposal of these materials is essential to block that disease pathway.

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 Stock². 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.

¹ APHIS has the authority to regulate how animal producers may move and dispose of Dead Stock. See 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 other point of concentration.”

² Sometimes referred to as “on-farm deads,” 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.

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 process used.³ 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 Administrator.

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,⁴ 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.

³ 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.

⁴ As noted in the January 2003 Notice on this topic, rendering reduces the volume of material by 64 percent. See 68 Fed. Reg. 2708.

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.⁵

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.⁶ Alkali in combination with heat is acknowledged as an effective means of reducing the infectivity of TSE agents and, based on pilot scale studies; the commercial scale application of these approaches is expected to be effective.⁷ 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 Secretary 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. 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.

The rule would require the regulated disposal of RAMs. These materials pose the most significant risk for transmission of BSE. 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,

⁵ 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.

⁶ Waste Reduction Inc. 2002 Biological waste management by alkaline hydrolysis. Technical Data Monograph. <http://www.wr2.net/technicaldata>.

⁷ Opinion of the European Commission Health and Consumer Protection Directorate-General Scientific Steering Committee adopted May 16, 2002.

even under the most stringent procedures or with the best of intentions. APHIS 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.

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.

APHIS 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 APHIS 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. APHIS 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 rules 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 rules would permit the Administrator or state regulator designees to inspect any Disposal Facility.

Environmental Impact

Analysis of Impacts

Paperwork Reduction Act of 1995

List of Subjects

9 C.F.R. Part 56.

Under the authority of the Secretary of Agriculture, it is proposed that part 56 be inserted as part of Title 9 of the Code of Federal Regulations as follows:

DEDICATED DISPOSAL FACILITIES

Disposal Renderers

9 C.F.R. § 56.1. 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 Secretary, 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.

9 C.F.R. § 56.2. Disposal Facilities.

(a) A Disposal Facility shall be licensed by the Administrator. A list of licensees will be published in the Federal Register and may be obtained from APHIS. A license may be applied for or renewed by submission of a written application for or renewal of license form to the Department in Washington, DC. 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 subsequent calendar year upon payment of such license fees as determined by the Administrator. All licenses not renewed during December of each calendar year shall expire on December 31 of that year.

(b) 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.

(c) 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.

9 C.F.R. § 56.3. 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.

9 C.F.R. § 56.4. Only Permitted Disposal Methods.

(a) 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:

(1) Controlled incineration as specified in Section 56.8.

(2) Alkaline digestion as specified in Section 56.9.

(3) At a properly permitted (state or federal) landfill following rendering as specified in Section 56.7.

(4) Other disposal methods resulting in the total destruction of the material as approved by the Secretary, 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 Secretary.

(b) Material rendered at Disposal Facilities may also be used for non-food/non-feed industrial uses as permitted by Section 56.10.

(c) 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.

9 C.F.R. § 56.5. 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.

9 C.F.R. § 56.6. Operations.

- (a) Once delivered to a Disposal Facility, RAMs shall be rendered, incinerated or digested in alkali within 72 hours.
- (b) 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.
- (c) 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.
- (d) 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".
- (e) All operations of the Disposal Facility shall be in conformance with local municipal ordinances and State regulations.

9 C.F.R. § 56.7. Rendering Procedures.

- (a) 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).
- (b) 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 shall be in conformance with Section 56.13.

9 C.F.R. § 56.8. 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.

9 C.F.R. § 56.9. 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 Secretary. Effluent discharges must meet all applicable waste water permits.

9 C.F.R. § 56.10. Acceptable Uses for Processed RAMs

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

- (a) All tallow and grease derived from rendered RAMs may be used as fuel, fuel feedstock, non-cosmetic oleochemical products and lubricants.
- (b) 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.
- (c) Proteins derived from rendered RAMs may be used as fuel.
- (d) 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 Secretary, or disposed of in a state or federally permitted landfill.
- (e) Dried effluent from the digestion of RAMs may be land-applied according to local, state and federal permits.
- (f) Other uses as approved by the Secretary.

9 C.F.R. § 56.11. Records.

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

- (a) A record which shall show as to all materials received:
 - (1) Name and address of person from which the materials were obtained
 - (2) 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.
 - (3) Identification number on shipping container, can, or other receptacle and the time and date of the delivery of materials to the facility.

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

(c) A record of the disposition of the final products of each 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 Administrator or a State regulator for inspection and copying during normal business hours and shall be kept for a minimum of two years.

9 C.F.R. § 56.12. Handling Materials.

(a) 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.

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

(c) 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.

(d) 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.

(e) 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.

(f) 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.

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

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

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

(b) 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.

(2) 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.

(3) 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 Administrator or a State regulator for inspection and copying during normal business hours and shall be kept for a minimum of two years.

9 C.F.R. § 56.13. Clean-out Procedures for Situational Disposal Facilities

(a) 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.

(b) 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.

9 C.F.R. § 56.14. Denaturing.

(a) Except as specified in Section 56.12(c), RAMs shall be denatured in accordance with the procedures set forth in 9 C.F.R. § 325.13.

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

Transportation

9 C.F.R. § 56.15. Limitation on Transporting Dead Stock and Specified Risk Materials.

(a) 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, Meat and Poultry Inspection Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 [this is the address set forth in a similar provision in 9 C.F.R. § 325.20(d)].

(b) 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.

9 C.F.R. § 56.16. Licensed Vehicle Fleet or Independent Contractor.

(a) 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.

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

(c) 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.

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

9 C.F.R. § 56.17. Cleaning and Sanitation of Vehicles.

(a) 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 Administrator. Vehicles cleaned and sanitized in this manner may then be used for the transportation of other materials and products.

(b) 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.

(c) 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.

9 C.F.R. § 56.18. Vehicle Cleaning Area.

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

(b) 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.

9 C.F.R. § 56.19. Shipping Containers, Cans and Other Receptacles.

(a) 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.

(b) 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 ANIMAL FEED" 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.

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

9 C.F.R. § 56.20. Records.

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

(1) Date and time of pick up.

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

(3) 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.

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

(5) 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.

(b) 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 Administrator 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

9 C.F.R. § 56.21. Inspection

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

9 C.F.R. § 56.22 Penalties

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

- (a)(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

(b) 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

(c) Each day of violation shall constitute a separate offense under this regulation.

9 C.F.R. § 56.23. Refusal To Issue or Renew, Suspension or Revocation of License.

(a) The Administrator 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:

- (1) 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;
- (2) Willful disregard or willful violation of this regulation or any rules or regulations issued pursuant thereto;
- (3) Willful aiding or abetting another in violation of these regulations or any rules or regulations issued pursuant to thereto;
- (4) A licensee allowing its license to be used by an unlicensed person or entity;
- (5) 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 Administrator that such person or entity has not been sufficiently rehabilitated to warrant the public trust;

- (6) Making material misrepresentations or false promises of a character likely to influence, persuade or induce in connection with the business of a licensee;
- (7) 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
- (8) Failure to possess the necessary qualifications to meet the requirements of these regulations for the issuance of holding a license.

(b) The Administrator may, upon its 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 Administrator shall, in writing, notify the applicant or licensee that a hearing will be held to determine whether the applicant or licensee is qualified to so hold a license, and shall afford the applicant or licensee an opportunity to be heard in person or by counsel.

(c) Such written notice shall be delivered to the applicant or licensee at least 10 days prior to the hearing, by personal service on the applicant or licensee by registered or certified mail, sent to the business address for the applicant or licensee shown in the latest correspondence to the Department. The complainant and applicant or licensee shall be afforded an opportunity to present, in person or counsel, such statements, testimony, evidence and arguments as may be pertinent to the charge or defense thereto.

(d) The Department may subpoena any person, and receive evidence in the same manner, who may have knowledge of the charges involved.

(e) In the case of a denial, suspension or revocation of licensure, the applicant or licensee shall be informed of the reasons for the denial and may appeal the decision in writing to the U.S. District Court within 20 days after receiving notification of the denial.

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