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January 11, 2008

Ms. Susan Dudley, Administrator
Office of Information and Regulatory Affairs
The Office of Management and Budget
EEOB Room 262
Washington, D.C. 20503

RE: Summary of comments about a final rule titled: Substances Prohibited From Use in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy (RIN: 0910-AF46)

Dear Ms. Dudley:

The National Renderers Association (NRA) appreciated the opportunity to meet with Mr. Kevin Neyland, Deputy Administrator, Ms. Fume Greigo and other OMB staff on December 13, 2007.

The NRA is the international trade association for the industry that safely and efficiently recycles animal agriculture by-products into valuable ingredients for the livestock, pet food, chemical and consumer product industries. NRA represents its members' interests to Congress, regulatory and other government agencies, promotes greater use of rendered products, and fosters the opening and expansion of trade between North American exporters and foreign buyers. NRA's membership represents more than 98% of the rendering capacity in both the U.S. and Canada.

The purpose of the meeting was to share industry concerns regarding the FDA proposed rule amending 21 CFR 589.2000 and prohibiting the use of certain cattle origin materials from all animal feed. The October 6, 2005 proposed rule refers to these prohibited materials as "CMPAF", which it defined to include: 1) the brain and spinal cord from cattle 30 months and older that are inspected and passed for human consumption; 2) the brain and spinal cord from cattle of any age not inspected and passed for human consumption; and 3) the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed. We believe FDA intends to finalize the proposed rule, although the agency may allow brain and spinal cord from cattle not inspected and passed for human consumption to be used in animal feed, if the age of such cattle can be verified to be less than 30 months.

NRA believes that additional safeguards against bovine spongiform encephalopathy (BSE) are unnecessary. FDA reported on October 3, 2007 that compliance with the current 21 CFR 589.2000 is extremely high—of the 6602 firms handling prohibited materials, none required official action after inspections and only 190 (2.9 %) had minor technical violations rule requiring changes in recordkeeping or conditions involving non-ruminant feeds. The Animal and Plant

Health Inspection Service (APHIS) of USDA concluded after the testing of more than 787,000 cattle that the number of cattle in the U.S. infected with BSE is extremely low. This high level of compliance combined with a very low incidence of BSE suggests that the risk of BSE in the United States is already negligible.

In our comments to FDA in 2005, the NRA provided data showing that implementing a ban on CMPAF would cost more than $127.7 million per year. Copies of this economic assessment, conducted and written by Informa Economics, were provided to OMB at our December meeting and previously. Because of increases in production costs and in the market value of finished rendered products over the past two years, we believe the cost of implementing and complying with the proposed regulations would now be even greater than originally estimated.

In addition to being unnecessary and expensive, the proposed rule is likely to have unintended consequences including animal and human health risks due to improper disposal of dead animals as a result of high priced or non-existent dead animal pick up because of the devaluation caused by the proposed rule. These impacts are also detailed in the 2005 Informa Economics assessment which is still very much relevant.

In follow up meetings with Dr. Richard Crowder and others at the Office of the U.S. Trade Representative, we learned that in spite of negligible risk improvement provided by the proposed rule and the significant added costs for the rendering, meat packing, and livestock producing industries, that the primary driving force moving this proposed rule toward implementation is the hope that it will open beef trade with Japan, Korea, and Russia. The NRA is very disappointed that meeting unreasonable trade demands may trump sound science and risk assessment as reasons to promulgate new and onerous regulation.

NRA does not know the extent of SRM removal required in the latest version of the final rule. However, there is no version of a "short list" or age cut off that would make SRM removal from dead stock plants practical, enforceable, or safe for plant workers. These impacts are detailed in a letter from NRA member Darling International, Inc. on January 3, 2008, which NRA agrees with.

In summary, NRA does not believe the proposed rule is necessary. We do not believe the rule is enforceable, and we believe it will be more expensive and have a greater negative impact on the environment than predicted by FDA. Ignoring the unintended consequences and poor cost benefit ratio in order to "hopefully, maybe" break the beef trade logjam with countries that have not negotiated in good faith would be ill advised. We encourage the administration not to implement the proposed rule.

Sincerely,

Thomas M. Cook

Thomas M. Cook
President, National Renderers Association

DARLING INTERNATIONAL INC.

Sent by facsimile: 202-395-6102

January 3, 2008

Ms. Susan Dudley, Administrator
Office of Information and Regulatory Affairs
The Office of Management and Budget
EEOB Room 262
Washington, D.C. 20503

RE: Summary of comments about a final rule titled: Substances Prohibited From Use in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy (RIN: 0910-AF46)

Dear Ms. Dudley:

Mark Myers and I appreciated the opportunity to meet with Mr. Kevin Neyland, Deputy Administrator, Ms. Fume Greigo and other Office of Management and Budget ("OMB") staff on December 13, 2007. The meeting was organized by the National Renderers Association ("NRA") and Mr. Myers and I represented Darling International Inc. ("Darling"), an NRA member and the largest and only publicly traded independent rendering company in the United States.

The purpose of the meeting was to share industry concerns regarding the Food and Drug Administration's ("FDA's" or "FDA") proposed rule amending 21 CFR 589.2000 and prohibiting the use of certain cattle origin materials from all animal feed (RIN: 0910-AF46). The October 6, 2005 proposed rule refers to these prohibited materials as "CMPAF", which it defined to include: 1) the brain and spinal cord from cattle 30 months and older that are inspected and passed for human consumption; 2) the brain and spinal cord from cattle of any age not inspected and passed for human consumption; and 3) the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed. We believe FDA intends to finalize the proposed rule, although the agency may allow brain and spinal cord from cattle not inspected and passed for human consumption to be used in animal feed, if the age of such cattle can be verified to be less than 30 months.

As we discussed during the December 13 meeting, Darling believes that additional safeguards against bovine spongiform encephalopathy ("BSE") are unnecessary. FDA has reported that compliance with the current 21 CFR 589.2000 is extremely high and the Animal and Plant Health Inspection Service ("APHIS") of the United States Department of Agriculture concluded after the testing of more than 787,000 cattle that the number of cattle in the United States infected with BSE is extremely low. This high level of compliance combined with a very low incidence of BSE suggests that the risk of BSE in the United States is already negligible.

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Darling understands, however, that FDA does intend to amend the list of materials in 21 CFR 589.2000 that are prohibited from animal feed. The purpose of this letter is to draw OMB's attention to what Darling believes to be flaws and oversights in FDA's proposal. Darling is especially concerned that FDA has underestimated the potential cost, unintended consequences and enforcement issues associated with the proposed changes to 21 CFR 589.2000.

In its comments to FDA in 2005, the NRA provided data that suggested that implementing a ban on CMPAF would cost more than $127.7 million per year. Copies of this economic assessment, conducted and written by Informa Economics, were provided to you at the conclusion of our meeting. Because of increases in production costs and in the market value of finished rendered products over the past two years, we believe the cost of implementing and complying with the proposed regulations would now be even greater than Informa Economics originally estimated.

The unintended consequences and enforcement issues associated with the proposed regulation promise to further inflate the cost to industry while diluting BSE safeguards already in force. It appears that FDA has not fully considered these issues because, in its proposed rule, FDA provided little guidance regarding the methods and procedures that would be used to enforce a ban of CMPAF, verify the age of cattle, or measure compliance with such a ban.

1. **Removal of Brain and Spinal Cord Alone is not Practical**

The proposed rule appears to assume -- incorrectly -- that it would be a simple and routine procedure to remove brain and spinal cord from cattle over 30 months and that the material that would constitute CMPAF would amount to 1.3 pounds per animal. Brain and spinal cord are not easily removed from the skull or vertebral column and complete removal of such tissues may not be attainable, even in cattle slaughter plants. Therefore, if the final rule provides that only the brain and spinal cord itself (i.e., approximately 1.3 pounds of material per animal) will constitute CMPAF from cattle over 30 months that were inspected and passed for human consumption, FDA will either have to develop methods for its complete removal (which do not currently exist), or develop a tolerance for this material remaining in the byproducts to be rendered.

Brain and spinal cord, in addition to other tissues from cattle 30 months and older, such as the skull, eyes, trigeminal ganglia, and dorsal root ganglia are defined by the Food Safety and Inspection Service ("FSIS") as specified risk materials ("SRM") and prohibited from food. FSIS does not require removal of the brain from the skull or the spinal cord from the vertebral column for compliance because the entire head (with the lower jaw and tongue removed) and vertebral column are prohibited. Accordingly, the head containing the brain, skull, eyes and trigeminal ganglia and the vertebral column containing the spinal cord and dorsal root ganglia are rendered along with other animal byproducts to make animal proteins and tallow. Unless FDA defines an appropriate tolerance level in the regulations for brain and spinal cord residues that may remain with the skull and vertebral column of cattle 30 months and older, these materials will also have to be considered as CMPAF. This will significantly increase the volume of CMPAF from

approximately 1.3 pounds to 53 pounds per animal (i.e., a 40-fold increase). The preamble to the proposed rule stated that approximately 7 million cattle 30 months and older are slaughtered in the United States each year. A 40-fold increase from 9 million pounds to 371 million pounds in the amount of CMPAF from cattle slaughter per year would increase the costs of complying with the proposed regulation far beyond the $127 million reported by Informa Economics and certainly beyond any FDA estimates.

Removing the brain and spinal cord from cattle that die on the farm or in transit will be extremely difficult because of tissue decomposition. If such materials are not removed, the entire carcass will be considered to be CMPAF. At present, protein products, such as meat and bone meal, produced from rendering animal byproducts and mortalities have value only when used as ingredients in animal feed. Prohibiting such use will cause renderers to either charge more for the removal, processing and disposal of cattle mortalities or discontinue such services altogether. According to Informa Economics, approximately 67 % of currently rendered cattle mortalities and other carcasses of cattle that are not inspected and passed for human consumption will no longer be rendered if FDA bans CMPAF. Therefore, alternative uses from products derived from CMPAF need to be developed to insure that CMPAF disposal can be maintained. These products have not yet been identified or developed and FDA does not appear to have given consideration to that issue.

2. The Age Verification Provisions are Problematic

Age verification is a critical factor that makes the proposed regulations unworkable as presently drafted. In the proposed rule, FDA specified that among cattle inspected and passed for human consumption, only those 30 months and older would contain materials classified as CMPAF. By contrast, all cattle not inspected and passed for human consumption would contain materials classified as CMPAF. We understand that in the final rule as submitted to OMB, FDA may not prohibit from animal feed brain and spinal cord material derived from cattle mortalities and carcasses of cattle not inspected and passed for human consumption when such carcasses can be verified to be less than 30 months of age. This provision was not included in the proposed rule and may have been added to address the rendering industry's disposal concerns by reducing the volume of CMPAF in that cattle that die before reaching 30 months of age could continue to be rendered.

The proposed recordkeeping requirement -- that renderers verify and document cattle age -- is, however, both unworkable and impractical. First, renderers do not have access to age data: this information is in the possession of cattle owners. Renderers have no means of requiring cattle owners to provide this information to renderers, or to verify its accuracy. Yet it is renderers that would be exposed to penalties and losses -- such as potentially devastating recalls -- in the event of incorrect age information.

FDA has also provided no guidance for renderers to follow when verifying age. Because the United States has not yet implemented a mandatory national animal identification system ("NAIS"), Darling is not aware of any independent means of certifying the age of cattle. APHIS

has proposed such a system, but implementation has been delayed. Dentition is sometimes used to approximate the age of cattle, but such methods are more predictive of physiological maturation than chronological age and are not good indicators to use for regulatory compliance. If, under FDA's final rule, renderers can accept cattle that die before they are 30 months of age, but must refuse older cattle, cattle owners will be encouraged to declare that all bovine animals that die on their farm or ranch are less than 30 months of age. In many areas of the United States, state and local regulations limit the options available for the disposal of cattle mortalities and designate rendering as the preferred option. If rendering services are no longer available for carcasses considered by FDA to be CMPAF, cattle owners will be forced to choose between falsely certifying the animal as less than 30 months of age or violating state and local carcass disposal regulations.

Darling believes FDA should develop procedures for cattle owners to use to determine, where necessary, and certify that cattle are less than 30 months of age. Even if such certification procedures are developed, however, and even if the final rule provides that renderers are shielded from regulatory risk by reliance thereon, Darling and other renderers still risk economic harm from product recalls and loss of goodwill if the owner intentionally or inadvertently falsifies the age of an animal. Under the proposed rule, renderers are responsible for assuring compliance without access to the information necessary to do so. If the information the renderer obtains is faulty or inaccurate, that renderer is subject to both regulatory and economic risk, with no practical way to protect itself from either.

We are not aware of any analytical methods to test for the presence of brain and/or spinal cord tissue in material to be rendered or in finished rendered products. Even if such methods are developed, it will not be possible to distinguish tissues from cattle over 30 months of age from those of younger cattle (i.e., distinguish between prohibited and allowable material). Without clear guidance from FDA, rendering companies may be forced to require certifications from large and small slaughter facilities that all animal byproducts to be rendered are only from cattle under 30 months of age and are inspected and passed for human consumption. Such a requirement would limit the marketability and salvage value of older cattle, including dairy and beef cows that have been culled from the herd. Even federally-inspected slaughter facilities may find it necessary to slaughter only cattle less than 30 months of age because FSIS may not have authority to enforce animal feed rules promulgated by FDA.

The real answer would be to implement a mandatory cattle identification system and make the identification information -- including cattle age -- available to all those in the market chain, including renderers. Only then could renderers have sufficient information to provide the verification and maintain the documentation required by the proposed rule. Until such an identification system is fully implemented, the age verification issues described above will continue.

Mandatory cattle identification is, however, unlikely to occur in the near future. APHIS has withdrawn plans for a mandatory system and is proposing a voluntary system instead. Congress further delayed implementation of NAIS when it approved less than 30 percent of the

$33.2 million requested by APHIS to support NAIS in fiscal year 2008. With limited funding, APHIS may choose to focus NAIS development on the animal industries best suited to implement such a system quickly and with the least cost to APHIS. Because the cattle industry is more diverse than the poultry or swine industries and cattle producers do not uniformly support NAIS, a national identification system for cattle will take longer to implement than for poultry and swine. Age verification will therefore be possible for poultry and swine much sooner than for cattle and, given its now limited resources, APHIS may choose to focus attention of NAIS for those species, rather than for cattle, thereby further delaying the cattle identification system necessary to implement the FDA proposed rule.

3. **FDA has also Underestimated the Impact of Banning CMPAF on the Markets for Finished Rendered Products**

Because of the compliance issues discussed in the previous paragraphs, the feed industry will have many of the same concerns about compliance that renderers will have. In order to reduce the potential for a product recall, feed manufacturers may require that all finished rendered products be free of brain and spinal cord material, even though such materials that are derived from cattle under 30 months of age are legally permitted in animal feed. This would increase the volume of material that is not rendered and that must be disposed of by methods other than rendering in order for renderers to maintain existing markets.

Meat and bone meal and other rendered products derived from CMPAF as well as any other cattle materials that the feed industry chooses to stop accepting will have little or no value. As a result, rendering companies will no longer accept such materials, including cattle mortalities. The disposal of such CMPAF that is not rendered has not been addressed by FDA or other federal agencies. The risks to human and animal health and the potential for damage to the environment if CMPAF is not properly disposed of outweigh any potential benefits derived from banning such material from animal feed. If prohibiting CMPAF from animal feed is warranted, its disposal must be regulated to assure these materials are properly removed and to facilitate enforcement of the requirements of the final rule. Without such federally-mandated, regulated disposal, FDA and other regulatory agencies will lose control over the CMPAF because such material will no longer be concentrated at rendering plants. All traceability will be lost.

Darling has provided evidence that the FDA's rule prohibiting CMPAF from animal feed is highly complex and has associated enforcement issues, significant costs to industry and basic questions about CMPAF disposal that have yet to be – and must be - addressed. FDA currently lacks sufficient resources and authority to address such issues on its own and will require support and cooperation from FSIS (meat inspectors to verify CMPAF removal from rendering), APHIS (implementation of NAIS for cattle and development of a federal plan for disposing of CMPAF), other federal agencies and state agencies. Support from the U.S. Congress will also be necessary to be sure that federal programs (such as NAIS) and resources needed to enforce a ban of CMPAF are adequately funded. As of this writing, and to the best of our knowledge, the necessary coordination and planning have not occurred.

In summary, Darling does not believe an adequate infrastructure currently exists in the United States for FDA to amend 21 CFR 589.2000 to prohibit certain cattle materials from animal feed as described in the proposed rule. Before such actions can be considered (1) a mandatory national animal identification system must be implemented to facilitate age verification; (2) tolerances established for brain and spinal cord residues in materials from cattle over 30 months that are to be rendered; (3) a federal plan for disposing of the CMPAF in a manner that continues to protect human health, animal health and the environment must be developed; and (4) alternative uses for products derived from CMPAF, particularly meat and bone meal, need to be developed to assure that CMPAF disposal can be sustained.

Respectfully,

C Ross Hamilton

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

Cc: Mr. Kevin Neyland, Deputy Administrator (202-395-7245)
Mr. Mark Myers
Mr. Tom Cook