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February 3, 2003

Dockets Management Branch (HFA-305) 03 FEB -5 A9:17
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No 02N-0273, Advanced Notice of Proposed Rulemaking "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed".

Dear Madam/Sir:

Darling International Inc., as one of the largest independent rendering companies in the United States, submits the following comments in response to the above Notice, issued by the US Department of Health and Human Services, Food and Drug Administration (FDA), Docket No. 02N-0273. Since 1997 when the FDA first advanced the Feed Rule prohibiting the use of certain mammalian proteins in ruminant animal feed, published at 21 CFR 589.2000 ("Feed Rule"), in order to further prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE) in the United States, Darling International Inc. has and continues to support all of the "firewalls" implemented by the FDA to prevent BSE from occurring. The measures promulgated by the FDA in 1997, were all developed using sound scientific principles; any additional modification to the current Feed Rule should do so as well.

As the Harvard Center for Risk Analysis concluded in a study released in November 2001 "...the U.S. is highly resistant to any introduction of BSE or similar disease. BSE is extremely unlikely to become established in the U.S."[1] They further reported that the Feed Rule was one of the most effective measures undertaken to prevent the spread of BSE in the U.S.

In the absence of BSE in this country, further additions to the Feed Rule are not warranted, absent complete industry compliance with the provisions of the current Feed Rule. Both the commercial feed industry and the rendering industry have been and continue to be committed to 100% compliance to the Feed Rule. The importance our industries placed on this issue was demonstrated before the agency stepped up inspections and compliance efforts in 2001, when the American Protein Producers Association (APPI) and the American Feed Industry Association (AFIA) developed their own inspection programs using third-party auditors.

02N-0273 C 28

[1] Cohen, J.T. et al. 2001 Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States Harvard Center for Risk Analysis, Harvard Scholl of Medicine and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskagee Uuniversitiy.

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Darling International Inc. is proud to be an active member of these organizations, who along with other related associations including the National Renderers Association (NRA), the Fats and Proteins Research Foundation (FPRF), the North American Rendering TSE Coalition are also submitting commits on behalf of the rendering and commercial feed industry.

Darling International Inc. believes that the current rule is more than adequate and that any modification to the current rule would not be warranted at this time. Rather, Darling International Inc. believes that active surveillance and rigorous enforcement of the current Feed Rule (including more vigorous enforcement actions against violators) will result in greater risk reduction than any or all of the proposed changes advanced by the FDA in the above Notice.

With regard to the individual areas of concern and specific questions advanced by the FDA, Darling International Inc. offers the following comments:

1. Excluding brain and spinal cord from rendered animal products.

The Food Safety Inspection Service in 2002 discussed the possibility of banning brain and spinal cord from human food in a thinking paper published last year[2]. However, it is illogical for FDA to ban materials from animal feed solely on the basis that such materials can not be used for human food. There are many ingredients, additives and/or pharmaceuticals that are not permitted for human use but have either agency approval or are generally recognized as safe for use in animals.

For the FDA to suggest that central nervous system tissues such as brains and spinal cords ("CNS tissues") be excluded from rendered animal products is illogical in the absence of sound scientific evidence of risk. Much of this misconception is derived from the European concept of specified risk materials (SRMs) which holds that CNS tissues are "high risk materials". Considering the fact that BSE has not been found to exist in the United States, it is incongruous for the FDA to require that CNS tissues be removed from animal feed. Indeed for the FDA to suggest that CNS tissues be removed from animal feed implies that the United States has SRMs (and, by further implication, BSE).

Darling International Inc. is concerned any FDA prohibition on the use of central nervous system (CNS) tissues as materials used to make feed ingredients (such as meat and bone meal) for non-ruminant animals will send the wrong message to domestic and export users of animal proteins. This directly conflicts with current efforts by agencies within the United States Department of Agriculture to obtain a Geographical BSE Risk ("GBR") assessment of "1" (highly unlikely to present a BSE risk): any other GBR classification would require SRMs (as defined by the European Union) to be removed in order to trade with countries in the European Union or third countries having the same or similar restrictions on imports. Any FDA prohibition on the use of CNS tissues in animal feeds would suggest to the rest of the world that the United States has "specified risk materials" which would result in a decrease in the demand for U.S. meat and bone meal.

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[2] Bovine Spongiform Encephalopathy (BSE) Current Thinking Paper: Notice of Availability. Federal Register (January 17, 2002; Volume 67, No. 12, page 2399).

Furthermore, a prohibition on the use of CNS tissues in feed ingredients will result in materials from animal mortalities to be banned as it not feasible to remove these tissues from decomposing animal carcasses with certainty. There are no federal regulations to insure that animal byproducts and mortalities are safely disposed of using methods that protect human and animal health and the environment. Improperly disposed of animal tissues provide an excellent medium for pathogens to proliferate and threaten human and animal health.

The cost of removing specified bovine offal was examined in 1996[3]. On average, it was determined that about 20 pounds of these materials would have to be segregated from each bovine carcass. In total this would create disposal issues for more than 1.7 billion pounds of CNS tissues and dead cattle combined. The total cost associated with such a prohibition was estimated to exceed $400 million (in 1996 dollars).

Age verification of live cattle (by teeth) is difficult and imprecise. Age can more accurately be determined by examining the degree of bone ossification, but this is only feasible in carcasses that have been split to reveal the rib cage and requires experience and training. Therefore, it is unlikely that requiring removal of CNS tissues only from cattle over 24 months of age will be feasible because it is difficult to do and even more difficult to enforce.

Total compliance to the Feed Rule will insure that CNS tissues are not fed to cattle or other ruminant animals. It is more important that the agency concentrate on compliance and enforcement of the existing regulations than on creating new rules that can not be effectively enforced and/or disrupt current practices that pose little risk.

2. *Use of Poultry Litter in Cattle Feed.*

Contamination of poultry litter with wasted or spilled poultry feed containing ruminant derived meat and bone meal poses little risk, considering that such a small amount of poultry litter is fed to cattle. This practice represents a very limited risk of exposing cattle to infectious materials, should BSE ever occur in the U.S.

There is no evidence to suggest that the infectious agent causing BSE can survive challenges due to pH and enzymes as it transits the gastrointestinal tract of poultry or livestock. Therefore, there is no scientific evidence to support prohibiting the feeding of poultry litter to cattle on this basis.

As presented in comments submitted by the NRA, contamination of poultry litter with wasted or spilled poultry feed containing ruminant derived meat and bone meal poses little risk. In their worst case scenario, each pound of poultry litter was calculated to contain no more 1.3 grams of ruminant meat and bone meal. The agency has already determined that the accidental feeding of less than 7 grams of restricted use meat and bone meal to cattle in South Texas posed an

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[3] Sparks Companies. 1996. The Economic Impact of Proposed Regulations Regarding Ruminant-Based Protein Products.

"exceedingly low" risk[4] because the meat and bone meal was of U.S. origin and "therefore not likely to contain infected material because there is no evidence of BSE in U.S. cattle".

Given the fact that BSE has not been detected in the U.S. and poultry litter contains only trace amounts of ruminant derived meat and bone meal, this practice poses little risk for the transmission or amplification of BSE should it ever occur in this country.

The poultry industry consumes about 43% (2.4 billion pounds)[5] of the ruminant meat and bone meal produced in the U.S. Any regulatory action that disrupts this outlet would jeopardize the disposal infrastructure for almost 22 billion pounds per year of mammalian tissues[5]. Darling International Inc. encourages the agency to base any regulations pertaining to poultry litter on sound science.

3. Use of Pet Food In Ruminant Feed.

It is unnecessary and would be highly disruptive to both the pet food and the rendering industries to require that pet food be labeled with the cautionary statement "Do not feed to cattle or other ruminants". The Pet Food Institute will address the economic effects of such a labeling requirement in their comments.

The pet food industry uses approximately 23% (1.3 billion pounds)[5] of the ruminant meat and bone meal produced in the U.S. This important market could be inadvertently lost when pet food manufacturers abandon meat and bone meal as an ingredient in order to avoid including the cautionary statement on their labels[5].

The philosophy used to draft the original Feed Rule was based on science and an understanding of pet food consumer demographics. These consumers purchase pet food in retail outlets and might not understand the difference between ruminant and non-ruminant animals. To include the cautionary statement on pet food would unnecessarily create confusion and heighten public concern about BSE, even though the disease does not exist in this country. .

If distressed or salvaged pet foods are currently being fed to cattle or other ruminant animals illegally, then Darling International Inc. urges the agency to intensify its enforcement actions to bring this segment of the industry into compliance with the Feed Rule.

4. Preventing Cross-Contamination

The issue of cross-contamination is addressed adequately in the Feed Rule. The adoption of regulations that require dedicated facilities would be redundant and unnecessary. It is the individual company's responsibility to comply with federal, state and local regulations, including compliance to the Feed Rule. The decision to have either dedicated facilities or to follow strict clean-out, flushing and sequencing protocols in order to be in compliance is a business decision.

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[4] Event shows volatility of BSE issue. Feedstuffs. February 5, 2001 issue.
[5] Sparks Companies Inc. 2001. The Rendering Industry: Economic Impact of Future Feeding Regulations.

Both the rendering and commercial feed industries have taken compliance to the feed rule very seriously and developed their own voluntary inspection programs using third party auditors. Both industries have reported commendable participation in these programs administered through APPI and the Facility Certification Institute.

Most rendering companies already use dedicated facilities for logistical and economic reasons. Similarly, commercial feed manufacturers have transitioned from mills making feed for multiple species to dedicated facilities that make either ruminant or nonruminant feeds in order to insure compliance. Some commercial feed companies have chosen to stop using MBM derived from ruminants in all of their facilities, regardless of the specie serviced. These trends are supported by survey data[6] showing a 46% reduction in the number of feed mills using meat and bone meal between 1999 and 2002.

Given the strong industry involvement in compliance to the Feed Rule, the agency should vigorously enforce the regulations rather than micromanage the issue by writing new superfluous regulations.

5. *Elimination of the plate waste exemption.*

The agency narrowly defined plate waste products to exempt "inspected meat products which have been cooked and offered for human food and further heat processed for feed (plate waste and used cellulosic casings)" from the Feed Rule[7]. Such a definition excluded garbage that might contain "high risk" tissues.

The agency also considered "plate waste" within the context of the Feed Rule to be is similar to the Association of American Feed Control Officials (AAFCO) definition for "restaurant waste"[7]. According to AAFCO, Restaurant Food Waste (*60.97)[8] is composed of edible food waste collected from restaurants, cafeterias and other institutes of food preparation.

When the Feed Rule was promulgated[9], the FDA defended the exclusion of plate waste based on the fact that a small proportion of meat is included in plate waste and plate waste represents a small proportion of ruminant feed. Additionally the heat and pressure used to process plate waste should further reduce risk of transmitting a TSE agent.

Removal of said inclusion may create undue concern and confusion about BSE among the consuming public. In the absence of BSE, it is illogical to ban a product that was safe for human consumption until it was left at the table, from use in animal feed.

Banning plate waste and garbage from animal feed in order to prevent or control Trichinosis, African Swine Fever, Foot and Mouth Disease and other endemic and exotic diseases could be justified. However, the agency does not have the authority to ban plate waste for these reasons

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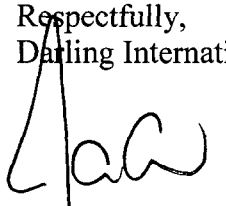
[6] Feed Management. 2003. Survey shows how mills are managed: Meat and bone meal use plummets. January issue. Volume 54 (no. 1): pages 14-17.
[7] Federal Register Vol 62. No. 108 (June 5, 1997) on page 30946.
[8] page 296 of 2003 Official Publication
[9] Federal Register Vol 62. No. 108 page 30946

and there is no scientific justification for banning plate waste to prevent or control BSE, when the disease has not been reported in the U.S.

Efforts by the Federal government to prevent the establishment and amplification of BSE in the United States have been successful largely due to the fact that an aggressive surveillance program has targeted animals that are most at risk. Coupled with a vigorous inspection and enforcement by this agency, the risk of BSE's occurrence in this country remains low. Darling International Inc. supports the Feed Ban, but sees no reason for expanding or revising it until such time as the risk of BSE occurring in this country changes. Darling International Inc. encourages the agency to vigorously enforce the Feed Ban in order to obtain 100% compliance.

Respectfully,
Darling International Inc.



James A. Ransweiler,
President