

November 21, 2001

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**VIA FAX & E-MAIL**

Dockets Management Branch (HFA-305)  
Animal Feed Rule Hearing  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852  
Attn.: Ms. Linda Grassie

Re: Substances Prohibited From Use in Animal Food or Feed;  
Animal Proteins Prohibited in Ruminant Feed.  
Notice of Public Meeting and Request for Comments  
Docket No. 01N-0423

Dear Ms. Grassie:

In response to the above Notice of Public Meeting and Request for Comments ("Notice"), Darling International Inc. submits the following comments concerning whether the FDA needs to implement new measures beyond the present animal feeding rule at 21 CFR Sec. 589.2000 ("Feed Ban").

Darling believes that, while the current feed ban is sufficient in principal, there are actions that the FDA should take to correct deficiencies and ensure compliance including:

1. There is no scientific evidence to support expanding the current feeding ban to include other rendered materials or to prohibit feeding rendered materials derived from ruminant animals to other animal species.
2. Develop, enhance, and maintain surveillance system guidelines that can quickly and accurately identify non-compliance and address such non-compliance through enforcement powers including, without limitation, fines and penalties.
3. Provide thorough training of federal inspectors on Feed Ban inspection guidelines to ensure that such inspections are conducted in a consistent fashion so as to avoid inconsistent and erroneous reporting.
4. Prohibit the reporting of "Raw Data" from compliance inspection reports.

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5. Require that only licensed rendering facilities be permitted to handle the disposition of dead animals and unprocessed viscera, bone, fat trim, meat trim, blood, feathers and other animal products or by-products that are deemed to be inedible or unsuitable for human consumption (known collectively as "Raw Materials").

Darling International Inc. takes the issue of biosecurity very seriously and recognizes that the rendering industry has a pivotal role in protecting animal and human health. Darling fully supports the current BSE prevention efforts developed by the FDA, APHIS and other federal agencies, even though no case of BSE has ever been found in the United States and complies with the terms of the current feed ban regulations set forth at 21 CFR 589.2000.

Darling International Inc. is one of the largest independent rendering companies in the United States, with facilities located in 22 states. Darling International Inc. is also a member company of the National Renderers Association (NRA), the American Protein Producers Industry (APPI) and the Fats and Proteins Research Foundation (FPRF).

Darling specifically comments on those questions presented by the FDA in the above Notice as follows:

1. **What additional enforcement activities, if any, regarding the present rule are needed to provide adequate public health controls? Are there any suggestions for ways to improve compliance with the rule?**

At the time it was implemented, the FDA noted that it would "implement a vigorous enforcement program" (62 FR 30936, at 30942, June 5, 1997) designed to prevent the use of proteins derived from mammalian tissues in ruminant animal feed. The regulatory effort was to create a mechanism designed to limit the ability of BSE to occur in this country, a disease that has never been detected in the United States. While not citing any specific penalty that it would impose, the agency has the ability to issue injunctions, impose criminal penalties and seize adulterated or misbranded product. However, to date, regulatory enforcement of non-compliance with the Feed Ban has amounted to little more than the issuance of warning letters.

In order to assure that the feed ban is measuring up to its intended goal, the FDA must be willing to diligently enforce industry compliance with the terms of the Ban. Rather than expanding the scope of the current Feed Ban to include more items, the FDA should develop and adhere to an enforcement policy that not only mandates compliant behavior but also penalizes non-compliance accordingly. The FDA must establish concise enforcement guidelines that provide for monetary penalties for non-compliance, as well as providing for other actions such as mandatory product recalls, cease and desist orders and/or suspension of operations until the deficiency is corrected or abated.

Agency inspectors (as well as "contract" inspectors from State agencies) must be trained in all nuances of the regulatory and inspection requirement to ensure consistency and credibility in inspection activities. Special attention should focus on familiarizing inspectors with the rendering process to avoid inconsistent inspections and subsequent dissemination of misinformation related to industry compliance to "the Rule".

In addition, inspection reports provided on the FDA web site must be modified to show compliance or non-compliance for inspected facilities. The release of raw survey and inspection data, as currently practiced by the agency, compounds the problem of misinformation. Without proper interpretation by the agency, much of this data only serves to confuse and mislead the public. If the published inspection reports clearly indicate whether or not a facility is compliant with 21 CFR 589.2000, the public's perception of compliance will be improved.

It would also be worthwhile for the agency to provide prompt, clear and concise feedback to the managers of inspected facilities regarding their compliance status to the Rule. Under the current inspection process, many facility managers do not know the inspection results. Increased communication with the regulated facilities will increase the likelihood of compliance with the Rules.

**2. Is the present rule at § 589.2000 adequate to meet its intended objectives? If not, what are its inadequacies? Are there additional objectives that this rule should now address? If so, what are these new objectives?**

When the FDA decided to prohibit the use of mammalian tissues in ruminant animal feeds as a precautionary measure to prevent the transmission of TSE diseases to ruminants (like BSE) it did so despite the fact that BSE has never been detected in the United States. Even while acknowledging the abundant scientific uncertainty as to the origin and transmissibility of the disease, the FDA nonetheless adopted the Feed Ban as a measure to prevent "the establishment and amplification of the disease should it ever occur in this country (62 FR at 30936)."

Darling International believes that the current Rule is adequate to meet the stated objectives. There is no scientific evidence to support expanding the current feeding ban to include other rendered materials or to prohibit feeding rendered materials derived from ruminant animals to other animal species. The current Rule, surveillance programs, import restrictions and differences in animal production and feeding practices between the United States and European countries, including the United Kingdom, collectively make the likelihood of BSE occurring in the United States negligible. Therefore, there is no need to re-open the Rule and to do so is neither scientifically justified nor warranted.

**3. Should the present FDA ban on the use of certain mammalian proteins in ruminant feed be broadened? If so, what should the new parameters of use be? Should the rule be broadened beyond ruminant feed? Beyond mammalian protein?**

Feed safety must be built on risk-based scientific expertise. The intent of the Rule was "...to prevent the establishment and amplification of BSE in the United States through feed. Because BSE has never been detected in the United States, the agency believes that the actions it has taken in this final rule will accomplish this regulatory objective (62 FR at 30946)."

Over the years, the FDA has had sufficient opportunity to re-evaluate the extensiveness of the Ban, upon the presentation of clear and convincing scientific evidence warranting such a re-evaluation. To our knowledge, no such evidence has been presented. Therefore, broadening of the existing Rule beyond ruminant feed or beyond mammalian proteins is not supported with scientific evidence and Darling International Inc. recommends that the FDA leave the scope of the existing Feed Ban as currently written.

**4. Should FDA require dedicated facilities for the production of animal feed containing mammalian proteins to decrease as much as possible the possibility of commingling during production?**

There is currently nothing that would warrant the establishment of dedicated facilities for the production of animal feed containing mammalian proteins. When the Feed Ban was first implemented, the FDA determined that dedicated facilities were not necessary so long as "adequate clean out" policies and procedures to prevent commingling were established in order for a facility to produce or handle prohibited and non-prohibited proteins. The FDA has recognized that adequate clean-out procedures for all equipment used in the manufacture and distribution of feeds containing mammalian and nonmammalian protein are essential to avoid contamination of ruminant feeds with prohibited materials. In addition to the agency's response to comments in the June, 5, 1997 Federal Register (Vol. 62), the FDA's Small Entities Compliance Guide for Renderers provides additional guidance regarding procedures for avoiding commingling/cross-contamination of materials.

Renderers currently use voluntary HACCP programs and Good Manufacturing Practices (GMPs) to ensure that commingling does not occur between prohibited and non-prohibited proteins. Renderers who can document that they are using established, written procedures (available for inspection by the agency) specifying clean-out protocols applicable to their system are compliant with Sec. 589.2000(e)(1)(iii)(B).

Procedures such as physical cleaning (e.g., vacuuming, sweeping, washing), the emptying and/or flushing of all transport and process equipment including the raw material receiving hoppers, conveyors, grinders, and cooker from the first point of commonality of raw material through the load-out system have been accepted by the agency as adequate clean-out measures. All flush material is considered prohibited product and treated as such. All subsequent material processed would be considered non-prohibited product.

In the absence of any compelling evidence that would warrant the need for dedicated facilities, the FDA should reinforce its existing program through increased surveillance and enforcement to make sure that adequate clean-out policies and procedures are followed to prevent commingling of products. The need for the dedication of specific plants capable of handling mammalian proteins should only occur in the absence of a facility's ability to follow policies and procedures designed to prevent commingling of materials.

**5. Should FDA require dedicated transportation of animal feed containing mammalian protein to decrease as much as possible the possibility of commingling during transportation?**

As stated in Darling's response to #4 above, there is currently nothing that would warrant the establishment of dedicated vehicles for the transportation of animal feed containing mammalian proteins where "adequate clean out" policies and procedures to prevent commingling are in place. In the agency's response to comments in June 1997, the FDA included haulers of animal feeds as being required to follow "adequate clean out" procedures to prevent commingling of products. Transporters, like renderers, must resort to a physical cleaning of all transport equipment in order to assure compliance with the Rule. Therefore, the debate surrounding the

need for dedicated versus undedicated transportation of mammalian protein is, in fact, an enforcement issue and does not warrant new regulations.

It should also be noted that, while it is inappropriate to transport both prohibited and exempted materials in the same vehicle, the requirement of dedicated transportation will markedly increase transportation costs associated with delivering animal proteins to customers to use in making poultry and swine feeds. To be in compliance, most common and contract carriers would find it necessary to discontinue back-hauling these animal proteins (a common practice among persons involved in the business of transporting agricultural commodities), thus increasing freight costs.

The relative risk posed by using undedicated transportation to transport prohibited and non-prohibited materials (without following appropriate clean-out procedures) is small in comparison to the risk associated with the unregulated disposition of Raw Materials, derived from ruminant animals by methods other than those used by licensed renderers (see Darling's response to Question 17). Disposal of these materials through landfills, compost facilities, improper burial or dumping undermines the Rule's regulatory intent to prevent amplification of BSE should it ever occur in the United States. However, establishing regulations requiring that Raw Materials be collected, transported and processed by licensed rendering companies, will reduce the potential for the establishment of BSE should the disease occur in this country.

**6. In order to improve production practices and increase assurance of compliance with the rule, should FDA require FDA licensing of renderers and other firms/facilities engaged in the production of animal feed containing mammalian proteins.**

Licensing of rendering facilities by the FDA would be acceptable, provided the Raw Materials are collected, transported and processed only by licensed rendering companies (refer to question number 17). Had the FDA mandated the licensing of rendering facilities at the time of the Feed Ban's inception, much of the confusion in inspections and enforcement that have subsequently developed would have been avoided. The agency would have known who the renderers were, the materials that each facility handled and produced and would have disregarded transfer stations (that handle commingled materials for a processing facility) and non-rendering plants, such as those handling used cooking oils to produce yellow grease and feed fats. Many states currently issue state rendering licenses and permits to operate, so additional federal licensing requirements does not appear (on the surface) to be unduly burdensome. Federal licensing could also help to advance the mutual credibility of the rendering industry and the FDA.

FDA inspectors should also have some familiarity with rendering facility operations. Educating inspectors would further eliminate erroneous noncompliance citations. If FDA is to retain control over ensuring continued compliance with the Feed Ban, FDA, APHIS and members of the rendering industry should jointly develop a training and educational program that would set forth inspection guidance for federal inspectors that are to inspect rendering facilities for compliance with the Feed Ban.

In scrutinizing regulatory compliance, the agency must be consistent in its application of the licensing requirements and clearly communicate said requirements to all parties concerned with compliance and enforcement. Inspection data released by the agency should reflect a final assessment of the data: the facility, its location, if compliant or not and if not compliant, what the violation was, whether it was corrected (or when it will be corrected) and whether or not any

penalties were levied. Penalties for non-compliance could range from warnings to monetary sanctions, injunctions and/or criminal penalties, based on the licensing criteria that the FDA would establish. Furthermore, licensing would help educate federal inspectors on the particular inspection criteria to be complied with by a rendering facility.

**7. Should FDA revoke or change any/all of the current exclusions for certain products allowed in the current rule at § 589.2000 (a) (1)?**

In the absence of any clear and convincing scientific evidence presented that would warrant the FDA's alteration of the scope of the existing Rule, including revoking or altering any of the materials excluded under the ban, Darling recommends that the FDA leave the Feed Ban unchanged.

**8. Should FDA add to the list of prohibited material in ruminant feed (i.e., add to the definition of "protein derived from mammalian tissues") poultry litter and other recycled poultry waste products?**

Darling believes no adjustment should be made to the current Feed Ban including the addition of other materials deemed to be prohibited thereunder in the absence of clear and convincing scientific evidence that would justify any such modification. Nevertheless, Darling believes that all comments related to this question are best answered by representatives of the poultry and related feed industries and defers to them accordingly.

**9. Should FDA remove the exemption for pet foods from labeling with the precautionary statements?**

Darling believes no adjustment should be made to the current Feed Ban, including changes in exemptions to the labeling requirements thereunder, in the absence of clear and convincing scientific evidence that would justify any such modification. Additionally, Darling believes that all comments related to this question are best answered by representatives of the pet food industry and defers to them accordingly.

**10. Should FDA extend its present record-keeping requirement beyond 1 year? If so, how many years?**

In 1997, the FDA determined that a one (1) year record retention requirement under §589.2000(h) (1) was sufficient for "determining whether a person is currently complying with the rule" (62 F R at 30946). It was the agency's position that any extension of the record retention period beyond one-year would have little practical value in determining the source of a TSE in an animal. Darling believes, at the outset, that there is no reason that would warrant the FDA extending the current record keeping requirements.

Notwithstanding the foregoing, any endorsement by the FDA of third-party audit programs developed by the rendering and feed industries for purposes of determining and certifying company compliance with the Feed Ban, should mandate that records be retained for a period of time equal to the validity of the industry's compliance certificate. It would make no sense for a renderer or feed mill to receive a compliance certificate from the third-party auditors that is

good for two years but only be required (under the Feed Ban) to have retained records for one year.

[Darling supports the use of third party audit programs and discusses this issue in its response to question 15, infra.]

**11. Should FDA change its rule to require labeling of protein-containing feed to specify what types of mammal was used in the production of the protein, e.g. "porcine MBM", "bovine MBM".**

No. As currently written, if material contains the cautionary statement, then it contains ruminant material, even if the majority of the raw material was pork or non-mammalian in origin. To label this type of material as "bovine material" would be mislabeling and in direct conflict with AAFCO labeling rules. As a result, compounded label terms would be necessary and create further confusion.

It would be acceptable to require that porcine material be so labeled, provided it can be verified to be 100% porcine. Materials containing any ruminant materials should continue to be labeled with the cautionary statement (Do Not Feed to Cattle or other Ruminants), without any designation as to specie. The presence of this statement implies that the product or feed contains ruminant material.

**12. In order to make the statement clearer, should the required cautionary statement on the label of products that contain protein derived from mammalian tissues and that are intended for use in animal feed be changed to read: "Do not feed to cattle, sheep, goats, bison, elk, or deer."?**

This is not necessary and would be redundant and costly to the industry.

**13. What new information is available on potential efficient, accurate analytical methods that may be used in detecting mammalian proteins, especially the prohibited mammalian proteins, in feed and what should the sampling parameters of such a program be?**

Caution is recommended in considering analytical methods for this purpose. The public will not accept any method that has potential for false negatives. Thus, the emphasis would be given to procedures prone to giving false positives, which would be unacceptable to the industry, because of the potential compliance issues and regulatory consequences. A false positive will be very difficult to verify or dispute. Adoption of analytical methodology as a regulatory tool would necessitate that the FDA develop methods and procedures that could be used to mitigate questionable or disputed results. It would also be necessary for the FDA to determine acceptable and unacceptable tolerances for prohibited materials in ruminant feeds.

Adoption of an analytical procedure to detect mammalian protein would require that exceptions to the Rule (such as porcine meal) be removed, which is neither logical nor scientifically justified. This action would also require the FDA to determine acceptable tolerance levels for mammalian protein.

Given the current status of the analytical testing industry in the development of tests to detect the presence of mammalian proteins or restricted use proteins, no single test is appropriate as a regulatory method and no battery of tests can conclusively confirm compliance or non-compliance.

**14. Regarding enforcing compliance with the rule, what further authorities, if any, would be desirable in order to enforce the rule adequately (civil monetary penalties, others)?**

No further authorities are currently required at this time. However, Federal enforcement of the regulations should be conducted in a consistent and uniform manner, pursuant to procedures and guidelines established by the FDA. All individuals charged with scrutinizing compliance with the Rule must be properly trained to recognize issues of non-compliance, so that there are no deviations from the regulations. Inconsistent enforcement by federal and state inspectors creates unnecessary confusion among the public and the regulated community.

**15. Regarding helping to increase compliance with the rule, what role, if any, should public or private certification programs play?**

Public or private third party certification programs should be endorsed by the agency as a means of verifying and encouraging industry compliance with the Rule. The use of such programs would help reduce the burden placed on the FDA's current surveillance and inspection system. The validity and value that such audits provide to public health can be greatly enhanced through FDA oversight and certification of the auditors. In the same manner that OSHA has established a program that provides for a state, using OSHA criteria, to conduct a facility safety inspection (upon request of the facility), so too could the FDA utilize such a third party inspection process. The FDA would be given access to compliance data obtained through these programs and those data used, along with FDA inspection data, to monitor industry compliance to the Rule.

Compliance with the Rule by the members of the rendering industry has recently been substantiated by the industry's independent third-party audit conducted by Cook & Thurber of Madison, Wisconsin.

**16. Regarding the import of feed, what should the restrictions on such import be (country specific? comparison between domestic and foreign controls?)**

Imported feeds and feed ingredients must be required to adhere to the same level of regulatory inspection and monitoring as domestic products to ensure that consumer protection is guaranteed. The FDA needs to maintain an enforcement program applicable to both domestic and imported feeds and feed ingredients to be sure the Feed Ban is followed.

Imported feeds and feed ingredients known or reasonably believed to have originated in a country known to have or suspected to have BSE must be banned outright until clear and convincing evidence to its safety can be established.

**17. Are there any other additional measures necessary to guard against BSE and vCJD in the United States?**

When the current Rule was promulgated, dead ruminant animals and unprocessed ruminant derived viscera, bone, fat trim, meat trim, blood and other animal products or by-products that are deemed to be inedible or unsuitable for human consumption (known collectively as "Raw Materials") were largely processed by the rendering industry. However, times have changed and an increasing number of animal producers, locker plant operators, meat processors and retail food chains utilize alternatives to rendering to dispose of Raw Materials. As a result the percentage of Raw Materials that are processed by the rendering industry is declining at an increasing rate. These unforeseen changes were precipitated by a cascade of marketing and economic factors resulting from adoption of the Rule, increased global concern about BSE and pressure from Europe on the international community to adopt European Union food safety principles and policies.

The Rule only prohibits the intended inclusion of restricted use rendered proteins in ruminant feeds. Ruminant materials that are disposed of through non-rendering means can still enter the food chain by a variety of means. Spreading composted Raw Materials, of ruminant animal origin, on land used for grazing and/or hay production is permissible under the current regulations. Further, domestic and wild ruminant animals may have direct exposure to unprocessed raw materials that have been improperly buried, composted or placed in landfills. This is especially concerning because scientist believe that Chronic Wasting Disease, a TSE affecting deer and elk, is transmitted when healthy animals are exposed to soil contaminated by the remains of an infected animal. It is thought that soil can remain contaminated for decades. These non-rendering practices are not currently regulated and could contribute to the "amplification of the disease should it ever occur."

The only way to insure that Raw Materials are biosecure with respect to BSE, as well as other infectious diseases is to regulate the disposition of all Raw Materials of ruminant origin. These materials need to be collected, transported and processed only by licensed rendering companies in order to limit exposure of domestic and wild ruminant animals to these Raw Materials. Because it is not common practice to feed either unprocessed Raw Materials or Raw Materials processed by methods other than rendering, it is not necessary to re-open the Rule in order to address this issue. Additional regulations enforced by the FDA or other federal agencies such as the Environmental Protection Agency or Animal and Plant Health Inspection Service are needed to regulate the disposition of Raw Materials derived from ruminant animals.

The origin and ultimate disposition of Raw Materials are not traceable when methods other than rendering are used. Rendering companies already possess the necessary infrastructure to allow for trace-back of Raw Materials and trace-forward of finished products. Only rendering companies are held accountable and required to document and maintain written records suitable for governmental agencies to trace Raw Materials back to their source and the finished products forward to the end-user. Except possibly for incineration, which is cost prohibitive and environmentally unsuitable, the alternatives to rendering for the disposal of Raw Materials do not provide adequate biosecurity against BSE or other diseases.

Before the agency expands the scope of the Feed Ban and/or removes any of the exempt products from the list, the FDA should ascertain that it has done everything *it* can do under the current

terms of the Feed Ban. In order to ensure biosecurity the FDA must (a) establish a federal licensing program that clearly delineates the necessary guidelines for a rendering company's operation, (b) regulate the Raw Materials by requiring that only licensed rendering facilities collect, transport and process the materials, and (c) develop and implement surveillance and enforcement guidelines that are consistently applied by properly trained inspectors. Utilization of FDA certified and approved third party auditors could provide assistance in ensuring industry compliance with the Feed Ban.

Darling International Inc. urges the Agency to regulate the disposition of Raw Materials and require that licensed rendering companies or other appropriate regulated entities collect, transport and process these materials. We are available to discuss this matter further at 800-800-4841.

Very truly yours,  
Darling International Inc.

  
James A. Ransweiler,  
President and Chief Operating Officer



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## FAX COVER

Date: 11/21/2001

To: **Dockets Management Branch**  
**Animal Feed Rule Hearing**  
**Docket No. 01N-0423** (301) 827-6870

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From: **Robert Frish, Corporate Counsel**

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Total Number of Pages Sent Including Cover Page: 21

**Comments:**

Attached, please find two (2) sets of written comments, submitted on behalf of Darling International Inc., regarding the FDA's Request for Comments on the Animal Feed Rule at 21 CFR 589.2000, **Docket No. 01N-0423**.

### CONFIDENTIALITY NOTE

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