TAB 41

DARLING INTERNATIONAL

THE FEDERAL FOOD AND DRUG ADMINISTRATION

NOTICE OF PUBLIC MEETING

AND REQUEST FOR COMMENTS

DOCKET NO.: 01N-0423

(66 Fed. Reg. 50929, October 5, 2001)

COMMENTS OF DARLING INTERNATIONAL INC:

SHOULD THE AGENCY IMPLEMENT NEW MEASURES BEYOND THE SCOPE OF THE PRESENT ANIMAL FEEDING RULE AT 21 CFR 589.2000?

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I am Robert Frish, Corporate Counsel for Darling International Inc., a rendering company with its corporate offices located in Irving, Texas. I would like to thank you for this opportunity to comment, on behalf of Darling International, on the status of the FDA's prohibition on the use of mammalian proteins in ruminant animal feeds. Please be advised that Darling International will be submitting written comments, supplementing today's presentation that more thoroughly responds to the agency's notice.

Ensuring biosecurity and the safety of the food supply is an overriding concern for Darling International. Every year, the American rendering industry provides a vital societal service in protecting animal and human health, effectively controlling and preventing the spread of diseases associated with animal tissues, by removing and processing the more than 50 billion pounds of animal and poultry by-products ("Raw Materials") generated by the livestock, meat and poultry industries. As one of the largest independent rendering companies in the United States, Darling International safely collects and processes more than 7% of the total annual volume of these Raw Materials through its facilities located in 22 states.

In 1997, the FDA prohibited the use of mammalian tissues in ruminant animal feeds as a precautionary measure in order to prevent the transmission of TSE diseases to ruminant animals (such as BSE), despite the fact that BSE had never been detected (and remains undetected) in the United States. Even while

acknowledging the abundant scientific uncertainty that existed as to the origin and transmissibility of the disease, the FDA nonetheless adopted the Rule as a measure to prevent "the establishment and amplification of the disease should it ever occur in this country." The agency further determined that the absence of compelling scientific evidence did not warrant banning the use of any other protein feed ingredients other than specified proteins derived from mammalian tissues in ruminant animal feeds.

Darling International believes that the scope of the current rule sufficiently meets its stated objectives. Experts agree that feed safety must be built on risk-based scientific expertise. There is currently no compelling, risk-based scientific evidence to support expanding the current feeding ban to include other rendered materials, eliminating the exemptions for certain ruminant proteins previously determined to present no risk (such as blood and blood products) or to prohibit the feeding of rendered proteins derived from ruminant animals to other animal species. The current Rule, surveillance programs, import restrictions and the marked 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. There is therefore no need to re-open the Rule and to do so is neither scientifically justified nor warranted. Rather than altering the current scope of the Rule, the agency should consider addressing the way in which they follow and enforce the Rule's parameters.

Much of the inconsistencies in the current surveillance system could have been avoided had the FDA initially mandated the licensing of rendering facilities. At the time of the Rule's inception, the agency would have known who the renderers were and what materials were handled and produced by each facility. The agency would have also been able to distinguish 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, and would have disregarded them from unnecessary inspection criteria. Many states currently issue state rendering licenses and permits to operate, so additional federal licensing requirements would not have presented an undue burden provided clear guidelines were established. Licensing could also assist in advancing the rendering industry's credibility.

It is up to the rendering facility to determine what type of facility it will be, depending not only on the raw materials handled but the type of finished proteins it seeks to produce. Just because a facility handles exempt raw material (such as porcine or poultry material), does not mean that it is going to sell exempt material. Once a facility declares whether it will handle exempt raw materials only, exempt and non-exempt raw materials in a manner consistent with the Rule, or commingled raw materials as restricted-use proteins, guidelines could be created to delineate the compliance parameters that must be adhered to.

At the same time, FDA compliance inspectors should be trained to be familiar with rendering facility operations and how such operations are performed under the Rule. Too often, the inspectors are unfamiliar with how the facility operates or inspect for issues that are not covered by the Rule, resulting in erroneous notations of non-compliance for that facility. FDA, APHIS and members of the rendering industry should consider jointly developing a training and educational program that would set forth rendering plant compliance inspection guidance for federal inspectors. Properly trained inspectors would further eliminate erroneous noncompliance citations and yield more accurate inspection data. Penalties for non-compliance could be created ranging from warnings, monetary sanctions, injunctions and criminal penalties based on the particular licensing criteria that the FDA would establish.

When the FDA established the Rule, it was noted that it would "implement a vigorous enforcement program" designed to prevent the use of proteins derived from mammalian tissues in ruminant animal feed. It was the agency's intent to create a mechanism designed to limit the ability of BSE to develop in this country. The Rule provides the agency with the ability to issue injunctions, impose criminal penalties and seize adulterated or misbranded product. However, to date, enforcement activity for non-compliance with the Rule has amounted to little more than the issuance of warning letters. Moreover, the

agency's compliance inspection reports reflect inconsistent enforcement of the regulations established by the Rule.

In order to ensure that the Rule measure up to the FDA's intended goal, the FDA must be willing to diligently enforce compliance with the tenets of the Rule in a consistent fashion. Instead of expanding the scope of the current Rule to include more items, subject to an inconsistent surveillance and enforcement program, the FDA should develop and adhere to a strong enforcement policy that not only mandates compliant behavior but also penalizes non-compliance accordingly. Clear and concise enforcement guidelines providing for monetary penalties for non-compliance must be established, along with provisions for other actions such as mandatory product recalls, cease and desist orders and suspension of operations until the non-compliant action is corrected or abated.

If you are going to have inspectors out there, it's important that they be thoroughly and properly trained in all nuances of the regulatory and inspection requirements to ensure consistency and credibility in inspection activities. Matters that are not governed by the rule should not be part of the scope of the investigation unless there is a direct impact on compliance, such as the measures in place to prevent commingling of materials. Special attention should focus on familiarizing inspectors with the rendering process to avoid inconsistent inspections and the subsequent dissemination of misinformation related to industry compliance to "the Rule".

There is a problem with sending out field staff to conduct inspections, who view their role as simply information gatherers, and they don't know the boundaries of what to inspect. The inspectors openly acknowledge that they know nothing about the rendering industry or the facilities that they inspect. They conduct the inspection of a company for compliance to a rule that they themselves are uncertain how that operation is supposed to behave in order to be in compliance.

The inspectors are fact finders who ask questions with an investigatory slant that may or may not be germane to the issue of compliance to the Rule. All of the information generated by their investigation is then sent "up the line" for someone else to interpret; this often includes the information gleaned that has no direct bearing on compliance. This type of information, otherwise irrelevant to compliance, gets posted by the agency, without proper interpretation and stimulates unnecessary and otherwise unwarranted public concern.

The inspection data posted by the FDA on their web site must show compliance or non-compliance for inspected facilities and disregard information that does not have any relevance to compliance. If the published inspection reports indicate whether or not a facility is compliant with 21 CFR 589.2000, the public's perception of compliance will improve.

It would also be extremely worthwhile for the agency to provide prompt feedback to the managers of inspected facilities regarding their compliance status to the Rule. Currently, many facility managers do not know the inspection results until after the agency has posted its findings on the Internet. Increased communication with the regulated parties will increase the likelihood of compliance with the Rules.

One issue of paramount concern that is outside the scope of the current Rule, is the status of the raw material itself. When the Rule was first 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 were mainly handled and processed by the rendering industry. Yet over the years, economic conditions and unforeseen marketing changes have negatively impacted the rendering industry, precipitated in part by the Rule, coupled with rising international concern about BSE and pressure from Europe on the international community to adopt E.U. food safety principles and policies. As a result, rendering facilities now charge for their services. This has prompted an increasing number of animal producers, locker plant operators, meat processors and retail food chains to utilize alternative methods for the disposal of these raw materials. In short, the percentage of these raw materials that are collected and processed by the rendering industry is steadily declining. If it doesn't go to a rendering facility, do you know where it will end up?

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.

The current Rule only prohibits the *intended* inclusion of proteins derived from mammalian tissues in ruminant feeds. Ruminant materials that are disposed of through non-rendering means, such as composting, landfill or on-site burial, can still enter the food chain by a variety of means. The spreading of composted raw materials of ruminant animal origin, on land that is used for livestock grazing and/or hay production is permissible under the current Rule. Domestic and wild animals, including ruminants, may have direct exposure to unprocessed ruminant raw materials that have been improperly buried, composted or placed in landfills. This is of particular concern because scientists believe that Chromic 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 believed that the soil can remain contaminated for decades. The unregulated use of non-rendering alternatives could lead to the "amplification of the disease" that the Rule was implemented to prevent in the first place.

While incineration is a viable option for disposal of these raw materials, it is both costly and environmentally unsuitable. Other alternatives to rendering for the disposal of Raw Materials such as composting, on-site burial or landfills, do not provide adequate biosecurity with respect to BSE, as well as other infectious diseases. The best means of attaining and maintaining biosecurity is to regulate the disposition of all raw materials of ruminant origin by having licensed rendering companies collect, transport and process them in order to limit exposure of domestic and wild ruminant animals to these Raw Materials. The regulation of these Raw Materials can be established independent of and in addition to the present feed Rule.

In conclusion, before the FDA expands the scope of the Rule and/or removes any of the exempt products from the list, in the absence of compelling scientific evidence to do otherwise, the agency should make certain that it has done everything it can do under the current terms of the existing Rule.

The agency should focus on how to improve performance and compliance under the present Rules parameters. There should be better-developed and concise surveillance and enforcement guidelines established by the agency, including the development and implementation of an appropriate penalty schedule that would mandate compliance. Federal compliance inspectors must be properly trained in

both the nuances of the Rule and how the Rule applies to the industry that they inspect. Establishment of federal licensing guidelines would further assist the agency in this direction.

Most of all, the agency must address the need to regulate the raw materials from the outset, by requiring that only licensed rendering facilities collect, transport and process the materials. To permit continued disposal of these materials through non-rendering means undermines the intent of the Rule: to prevent "the establishment and amplification of the disease should it ever occur in this country."