PET FOOD INSTITUTE
2025 M Street, NW, Suite 800 • Washington, DC 20036 • (202) 367-1120 • FAX (202) 367-2120 • www.petfoodinstitute.org

OFFICERS

Chairman
Robert Wheeler

Vice Chairman
John Curtiss

Secretary
Robert Kelly

Treasurer
Richard Shields

Executive Director
Duane Ekedahl

BOARD OF DIRECTORS

American Nutrition

Bil-Jac Foods

Dad's Pet Care

Del Monte Foods

Doane Pet Care

Hill's Pet Nutrition

The Iams Company

Kraft Foods North America

Masterfoods USA

Menu Foods

The Meow Mix Company

Natural Balance Pet Foods

Nestle Purina PetCare Co.

Nutro Products

Old Mother Hubbard

Pro-Pet

Sunshine Mills

November 21, 2005 1832 5 NOV 22 A10:12

VIA EXPRESS MAIL

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 or Madam:

The following comments to the above referenced docket number are submitted on behalf of the Pet Food Institute (PFI). PFI is the national trade association representing the manufacturers of dog and cat food in the US, a $14 billion industry.

Before addressing the specific areas for which the Food and Drug Administration seeks comments, PFI would like to commend the agency for taking the bold steps contained in the proposed rule. Specifically, by prohibiting the inclusion of Specified Risk Materials (SRMs) in all animal feed, including pet food, FDA will make what is already a miniscule risk of BSE transmission in the United States even smaller. In addition, the prohibition on SRMs in animal feed will also help US producers maintain the high level of confidence pet owners throughout the world expect from US-made pet food products.

For the purposes of these comments, PFI adopts FDA's proposed definition of SRMs to include brain and spinal cord from cattle 30 months of age and older; the brains and spinal cords from cattle of any age not inspected and passed for human consumption; and the entire carcass of cattle not inspected and passed for human consumption if the brains and spinal cords have not been removed.

For ease of reference, PFI has divided these comments into three sections. The first section details the basis for PFI's support of the proposed rule banning SRMs in all animal feed. These reasons have been previously presented to FDA in comments submitted on August 6, 2004.

02N-0273

C 118

The second section of these comments focuses on areas for which FDA specifically seeks comments. These areas include:

- The need, or lack thereof, for broadening the definition of SRMs;
- SRM removal from cattle that have died other than by slaughter;
- The permitted use in animal feed of tallow containing less than 0.15 percent protein; and,
- The requirement for record keeping by renderers to document the proper disposal of SRMs.

In these comments, PFI will ask the agency to exercise regulatory discretion by allowing the harvesting of tissue from cattle where it is not possible to remove SRMs. PFI will also repeat its request that FDA take the opportunity presented by this proposed rule to clarify that the regulations contained in 21 CFR 589.2000 do not require pet food manufacturers to maintain records on retail sales and distribution of pet food products.

Support for the Removal of SRMs from All Animal Feed

PFI's comments submitted on August 6, 2004, in response to the FDA's Advance Notice of Proposed Rule Making (Docket Number 2004N-0264) set forth the reasons why we believe the removal of SRMs from all animal feed, including pet food, is critical to protecting both human and animal health. The summary list of those reasons bears repeating here:

> Simply put, removing all SRMs from ingredients used in animal feed will:
>
> 1) Exclude the most potentially infective tissues from all feed;
> 2) Remove the opportunity for the accidental or intentional "contamination" of ruminant feeds with potentially infectious materials;
> 3) Remove concerns regarding the potential contamination of poultry feed with infective material . . .;
> 4) Eliminate the need for removing the plate waste exemption . . .;
> 5) Eliminate the need for dedicated facilities and transportation, since the potentially infectious material is no longer present;
> 6) Continue to allow the use of non-ambulatory disabled and dead stock cattle as sources of animal feeds by removing potentially infectious materials;
> 7) Make enforcement of the [new] feed rule clear and effective; and,
> 8) Establish animal feeding rules that are much more consistent with those of [US] trading partners, leading to re-opening of many borders closed to US products, ruminant-based or otherwise.

As the above reasons illustrate, the removal of SRMs as now proposed would prevent the inadvertent or intentional inclusion of potentially infective material in ruminant feed. PFI fully supports this aspect of the proposed rule and believes FDA has acted in an appropriate manner to help add additional layers of protection to animal and human health.

Comment Request Sections

Many of the sections on which FDA seeks specific comments have already been addressed, generally, by the previous section. PFI offers the following comments to further illustrate support for the proposed rule or to suggest possible changes and clarifications in certain sections.

Expanded Definition of SRMs

In the proposed rule, FDA seeks comments on the need to expand the current definition of SRMs. PFI believes the agency has adequately explained its reasoning for proposing its definition for SRMs. This list conveys the additional risk mitigation expected by US consumers and trading partners while resulting in less disruption to animal feed production, rendering and slaughter operations.

As FDA correctly points out in the proposed rule, the current SRM list reduces potential infectivity by 90 percent and would dramatically reduce the potential for new cases of BSE, according to predictions based on the Harvard-Tuskeegee Model. Therefore, PFI fully supports the proposed rule's definition of SRMs and believes no changes to the definition are required.

SRM Removal from Non-slaughtered Animals

PFI supports the FDA decision in the proposed rule to exercise its regulatory discretion over the use of material in animal feed from cattle not presented for slaughter. PFI believes it is appropriate that SRMs be removed from all cattle intended for use in animal feed. PFI believes the rule allows processors the flexibility to salvage tissues from the carcass of cattle intended for use in animal feed when the brain and spinal cord are removed prior to or during such processing.

Tallow

PFI supports the proposal to require tallow contain no more than 0.15 percent impurities. This requirement in also consistent with many international requirements for tallow and will facilitate trade in US-made tallow and tallow-containing products. PFI would urge the agency to adopt this section of the proposed rule without modification.

Recordkeeping Requirements

PFI agrees with the proposed rule requirements that renderers must kept records for one year to ensure prohibited materials are not included in animal feed. One year is an adequate period of time given the limited time period such materials could conceivably be used.

One area, however, for which PFI would urge FDA to take the opportunity presented by this proposed rule is to correct the perception by some regulatory agencies that the original 1997 rule required records for individual retail pet food transactions. Specifically, PFI would request the FDA modify 21 CFR §589.2000(c)(4), or other relevant sections, to explicitly state that records on retail sales of pet food are not required.

PFI has previously made this request, most recently on March 22, 2005. The contents of those comments set forth the reasoning behind this request:

> Since the implementation of the 1997 rule to prevent the spread of BSE in the United States, PFI has heard complaints from its members and retailers that state inspectors have cited them for a perceived failure to keep records in the individual sales of pet food products to consumers. PFI believes the Agency never intended the record keeping requirements of the rule apply to retail sales of pet food and strongly believes the Agency should take this opportunity, while other changes to the rule are under consideration, to make an editorial clarification to expressly state that records are <u>not</u> required for individual retail sales of pet food.
>
> PFI would propose the text in the following section of the rule be modified to expressly state the pet food sold through retailers, including veterinary clinics, feed stores and online, is not subject to the recordkeeping provisions. The specific section, 21 CFR §589.2000 (c)(4), currently reads as follows:
>
>> Pet food products that are sold or intended for sale at retail and feeds for nonruminant laboratory animals are exempt from the labeling requirements in paragraphs (c) and (d) of this section. However, if the pet food products or feed for nonruminant laboratory animals are sold or are intended for sale as distressed or salvage items, then such products shall be labeled in accordance with paragraph (c) or (d) of this section, as appropriate.
>
> PFI believes the Agency never intended for the record keeping requirement to apply to direct-to-consumer sales of pet food for non-ruminant use. Therefore,

PFI would request the Agency clarify the rule's coverage by adding the following text to 21 CFR §589.2000 (c)(4):

> There are no record-keeping requirements for products exempted from labeling. However, if the pet food products or feed for nonruminant laboratory animals are sold or are intended for sale as distressed or salvage items, then record-keeping requirements contained in paragraph (c) of this section shall be required.

PFI continues to believe that any requirement for retail record keeping "serves no useful purpose," as the agency so aptly put in the preamble to the 1997 rule.

Conclusion

PFI commends the Food and Drug Administration on the appropriate risk mitigation strategy in the current proposed rule. By prohibiting the inclusion of a defined list of specified risk materials in all animal feed, including pet food, FDA has taken an important step to further reduce the already remote risk of BSE transmission in the United States. The additional proposed regulations will add further assurances to consumers here and abroad while imposing the least disruptive changes on producers. Finally, the addition of language clarifying the intent of the record keeping provisions in the original 1997 rule will free retailers of an unintended and unnecessary record keeping burden.

Sincerely,

Duane Ekedahl
Executive Director

cc: Randy Gordon, National Grain & Feed Association