



PET FOOD INSTITUTE

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

7721 01 NOV 21 19:27

November 20, 2001

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

Re: Comments by the Pet Food Institute to
Food and Drug Administration Notice on
21 CFR §589.2000 (Docket No. 01N-0423)

OFFICERS

- Chairman
Dan Reid
- Vice Chairman
Peter Cheney
- Treasurer
Doug Cahill
- Secretary
Jim Scott
- Executive Director
Duane Ekedahl

BOARD OF DIRECTORS

- American Nutrition
- Best Feeds
- Bil-Jac Foods
- Dad's Products Co.
- Doane Pet Care
- Friskies PetCare Co.
- Heinz Pet Products
- Hill's Pet Nutrition
- The Iams Company
- Kal Kan Foods
- Menu Foods
- Nabisco, Inc.
- Old Mother Hubbard
- Pet Life
- Pro-Pet
- Ralston Purina Company
- Texas Farm Products

Dear Sir or Madam:

The Pet Food Institute (PFI), which represents the manufacturers of 95 percent of the dog and cat food produced in the United States, a \$12 billion industry, offers the following comments to the Food and Drug Administration's October 5, 2001, Federal Register notice. Members of PFI have and will continue to support the agency's efforts to prevent the introduction and possible amplification of bovine spongiform encephalopathy (BSE) and other related transmissible spongiform encephalopathies (TSEs) in the US. PFI has a long history of working with the various state and federal agencies to accomplish this and other critical human and animal health goals. However, PFI members do not believe changes to the current rule contained in 21 CFR §589.2000 are required.

Since the agency implemented the prohibition on feeding certain mammalian proteins to ruminants in 1997, much about BSE has changed. Additional countries in Europe and most recently Japan have reported cases of the disease. However, one constant, for which

01N-0423

CH20

the agency deserves much of the credit, is that the US remains free of BSE. Not one case of BSE has been detected in this country despite the most aggressive testing program of any nation that does not have the disease, conducted in accordance with the Office of International Epizootics (OIE) standards. This underlying fact should be the foundation upon which the agency bases all decisions regarding amendments to the 1997 rule.

Specifically, since the US is BSE-free and the current rule is being enforced, the rule does not need to be changed. Changing the requirements of 21 CFR §589.2000 at this point in time, without additional compelling scientific evidence or risk analysis, could unnecessarily undermine public confidence in the extraordinary efforts the FDA and other federal and state agencies, as well as the industry, have taken over the past four years.

Recently released FDA compliance statistics highlight the progress made toward 100 percent compliance with the current rule. This data reveals an overall improvement in the compliance rate of inspected facilities. By making unnecessary changes to the rule now, the agency would need to expend significant resources reinspecting what are now compliant facilities and reeducating the industry and public about what is required under any new rule. Since the US does not have BSE, those resources would be better used toward the agency's 100 percent compliance goal using the current regulation.

As to the specific issue of adding a cautionary statement only to retail pet food, PFI will provide additional support for the continued labeling exemption for pet food intended for retail sale in response to Question 9. It should be further stressed that the use of such a statement on retail pet food will only serve to unnecessarily alarm consumers and would make pet food the only retail product sold in grocery stores and other outlets with

such a label.¹ However, salvage and distressed pet food must, under the current regulation, be labeled "Do not feed to cattle or other ruminants."² This is the appropriate and effective placement for such a cautionary statement since pet food for retail sale is not intended for ruminant feed.

The members of the Pet Food Institute thank the agency for the opportunity to provide detailed responses to the agency's inquiries. PFI recognizes the efforts of the Food and Drug Administration over the past four years in educating the industry and the public on the importance of the 1997 rule. This rule stands as an important barrier between the United States and the possible spread of a devastating animal disease. PFI members stand ready to give the agency further assistance in reaching its goal of 100 percent compliance.

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

Since PFI believes the current rule is adequate in preventing the introduction and spread of BSE in the United States, no additional activities are required. Additional steps, however, should be taken to educate producers and distributors on the agency's activities to prevent the spread of the disease and additional funds should be made available to FDA for either direct or state-contracted inspections of affected

¹ For example, in research conducted in 1997, PFI found that a large majority of consumers believed a cautionary label meant the product was in some way hazardous to their pet. Additionally, some consumers mistakenly believed their dog or cat was a ruminant. Survey results are provided in response to Question 9.

² For the purposes of these comments, two definitions are necessary. Salvage pet food is defined as product that is still under the direct control of the manufacturer and has not been distributed for retail sale. Distressed product is defined as products in the retail establishments that, for one reason or another, e.g. packaging damage, length of time since production, or other similar reasons, are no longer available for sale as first distributed. These products are also referred to as "unsalables".

facilities. The recently released inspection statistics showing increased compliance illustrate the success the agency has had in educating producers about the regulation. Changing the rule at this time would require a complete overhaul of the current inspection procedures, necessitate additional inspector training and further delay the agency's goal of 100 percent compliance.

Increased emphasis on enforcement of the rule, however, is necessary to ensure that those individuals and firms that are misusing products, unintentionally or not, containing ruminant protein are found and that and future misuse is stopped. Pet food companies are taking steps to deal with salvage materials, see Note 2, and have asked distributors to do the same with distressed products. However, PFI and the pet food industry are limited in their ability to require such labeling without educational assistance/enforcement directly from FDA. Educational and enforcement activities undertaken by the agency for food distributors must indicate that all unsalables containing ruminant materials, human food and pet food, are subject to rules regarding labeling and that the required record-keeping is done to protect public health.

2. *Is the present rule at Sec. 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?*

The current rule is adequate to meet the intended objective of preventing the amplification of BSE, should it ever be found in the United States, and should not be changed. The current rule includes restrictions on the use of ruminant proteins and provides requirements for manufacturing controls on the use and distribution of those restricted use proteins, going far beyond only labeling and record keeping requirements. In addition, the agency's Guidance for Industry further aids in understanding and complying with the regulation. As one of the three "firewalls" designed to protect US cattle and ultimately public health since the rule was

implemented in 1997, the agency and all affected producers have worked towards 100 percent compliance. Changes to the rule now would further delay this effort and increase the time for achieving this goal.

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?*

The current exemptions contained in the 1997 rule are appropriate and based on sound science and risk assessment. Any additions to the list of prohibited materials must be scientifically justified.

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

The additional burden of this requirement would not reduce the already rare incidents of commingling feed materials. Under the current regulation and guides, facilities handling mammalian protein are already required to have cleanout and segregation systems in place to prevent comingling. The enforcement of the system segregation requirements in the current rule is the best method to help prevent comingling.

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

PFI believes the current requirements for the transportation of feed ingredients is adequate to prevent commingling. The proper enforcement of existing requirements and the continued education of individuals engaged in feed and ingredient transport

of their responsibilities under the rule would be more effective and efficient than a dedicated transportation requirement.

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 protein?*

Mammalian protein is a safe and nutritious feed ingredient, and its use is restricted only from ruminant feeds. Therefore, facilities engaged its production and use should not be licensed by the agency. Rather than add an additional layer of recordkeeping to an already complex process, the agency should use its resources to achieve 100 percent compliance with the current rule. Under current state laws, these facilities are already required to hold a license as a producer of animal feed. FDA licensing would only add further complexity and burden to the agency and the industry while lacking any useful purpose in meeting the agency's goals under the rule.

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

PFI believes that changes to the current rule are not necessary and there is no need to make alterations to the list of product exclusions currently covered by the rule.

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?*

Since there is no scientific evidence linking the infectious BSE agent to transmission through poultry litter or other recycled poultry waste products, PFI believes there is no need to increase the list of prohibited materials. Recycled poultry waste

products, though not used in commercial pet food products, are valuable feed ingredients.

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

PFI supports the agency's 1997 decisions and believes there is no reason to change the exclusion for cautionary labels on pet food sold at retail. The reasoning for excluding pet food sold at retail from the cautionary label requirement was made clear in the agency's preamble to the 1997 rule:

FDA agrees that the cautionary statement serves no useful purpose on pet food and feed for nonruminant laboratory animals and has amended the rule by creating a new Sec. 589.2000(d)(4) to exclude pet food products that are sold or intended for sale at retail to non-food producing animals and feed for nonruminant laboratory animals. These products typically cost substantially more per ton than most complete feeds intended for food-producing animals. Therefore, there is little, if any, risk that pet foods or feeds for nonruminant laboratory animals will be purchased at full price for use in ruminant rations. (62 Federal Register 30955, 06/05/97) [emphasis added]

The agency went on to create a requirement that distressed and salvage pet food be labeled with the cautionary statement "Do not feed to cattle or other ruminants." The reasons for the agency decisions have not changed

Additionally, as stated by the US Department of Agriculture, BSE is not present in the United States. The risk of BSE occurring in this country is lower now than in 1997 due to the agency's efforts at enforcing the rule now under review. Since there is a miniscule risk of ruminant protein-based pet food being sourced as feed for ruminant animals, coupled with an absence of the disease, there is no need for a cautionary statement on pet food sold at retail.

As a PFI representative testified at the October 30, 2001, hearing, the agency should not remove the exemption for pet food sold at retail. Salvage and distressed

pet food should continue to be labeled according to the regulation since it could be incorporated into feed for food-producing animals. The Pet Food Institute has and will continue to educate its members, retailers, and other possible users of salvage and distressed pet food of the requirements under the current regulation. Examples of this education include letters sent to all members of the National Association of State Departments of Agriculture, a letter delivered to Food Marketing Institute members during a food safety meeting, guidance provided to the National Milk Producers Federation and communication to major retailers of their responsibilities under the rule.

Since PFI and other organizations are actively working to prevent the possible inclusion of salvage or distressed pet food in ruminant feed, which is only a minute amount of product intended for retail sale, the use of a cautionary label on retail pet food is not necessary.

In addition, pet food is the only product covered in the regulation that is sold at retail in grocery stores, pet shops, etc. PFI-commissioned research indicates the inclusion of such a label statement would have a serious detrimental effect on pet food and other meat-containing products. Specifically, consumer surveys revealed the following could occur if the statement "Do not feed to cattle or other ruminants" was included on retail products:

- 71% of respondents would buy something else other than pet food if they saw this label on pet food;
- 68% of respondents would be concerned or very concerned about the safety of the pet food if such a label was on the package;
- 57% of respondents did not know if dogs and cats were considered ruminants;
- 40% of respondents would be concerned or very concerned about the safety of humans eating beef and lamb as a consequence of this label appearing on pet foods.

As these responses indicate, a large number of consumers would draw incorrect conclusions from such a label. Arising from their mistaken view that pet cats and dogs are ruminants, or that such a label indicates an inherent hazard in the product,

a majority of consumers would alter their purchasing decisions because of a cautionary statement that would not add any added BSE protections. When purchasing "something else" consumers might not purchase a pet food product carrying a cautionary statement, but would consider moving to some "home-made diet" that is highly unlikely to meet the complex nutritional needs of the pet, resulting in deficiencies that commercially produced pet food is designed to prevent.

Another consequence of this label on retail pet foods containing ruminant protein ingredients may be a consumer shift to pet food products that do not contain those ingredients and, therefore, would not carry the cautionary label. This unintended shift could further disrupt the marketplace for ruminant protein ingredients and affect not only pet food manufacturers but renderers, meat processors and other related industries. Because the agency has had success in increasing compliance with the rule on the part of feed mills, renderers and other processes, as illustrated by its own statistics, new prevention measures are not necessary.

Further, when salvage or distressed pet food is found in commerce or distribution and is labeled as a different product; or is improperly mixed with other ingredients; or is being used as feed for cattle or other ruminants, the agency or appropriate state authorities must take immediate action to stop the misuse, mislabeling or mishandling of the material. However, as previously stated, the amount of distressed pet food possibly included in ruminant feed, even taking into consideration anecdotal reports, is so small in comparison to other issues that it does not warrant special attention.

10. *Should FDA extend its present recordkeeping requirements beyond 1 year? If so, how many years?*

The current recordkeeping requirements are adequate to prevent and contain potential feed contamination incidents. In each of the most recent examples, the

company in question has been able to use its records to completely trace the disposition of questionable feed. Expanding the recordkeeping requirement beyond one year will not increase the responsiveness of the industry to a potential problem and will only increase an already detailed recordkeeping requirement, especially since the original recordkeeping requirements were designed to "facilitate compliance with the rule."

The agency should also consider that removing the exemption for pet food sold at retail could force retailers to maintain the same records currently applicable to distressed and salvage materials. These requirements, while critical for distressed and salvage material, would be onerous when applied to retailers, would cause unnecessary consumer concern, would provide no useful information, and would result in a dramatic increase in record keeping noncompliance.

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

PFI believes the current ingredient definition procedures used by the Association of American Feed Control Officials (AAFCO) are appropriate and provide adequate information. Meat and bone meal, for example, is presumed to include restricted use protein and therefore is prohibited from ruminant feed. Meat and bone meal described in this question may be labeled as such when it can be identified as species specific. Changes to the nomenclature of this and other ingredients would only add a further unnecessary burden of testing and verification procedures.

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?"*

PFI is unaware of any confusion on the part of feed purchasers caused by using the term "ruminants" in the cautionary statement when placed on feed for food-producing animals.

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?*

PFI is unaware of any new information on detecting mammalian proteins in feed and defers to members of the scientific community for explanation on such methods.

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?)*

PFI believes the agency, working independently and in conjunction with state officials, has the authority necessary to educate producers and distributors about the requirements of the rule, as currently written, and enforce its compliance. The agency should not request additional authority for fines or other penalties but should devote its resources to compliance activities, hiring additional inspectors and developing additional coordinated inspections with state officials.

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

The rules established by the agency prohibiting the inclusion of certain mammalian protein in ruminant feed are fully described in the Code of Federal Regulations and related Guides for Industry. Since these regulations are legally binding on all feed producers, handlers, mixers, renderers, etc., there is no need for additional private certification. Compliance with the regulation is required by the agency, which has enforcement abilities at its disposal. The use of third-party certifications is, therefore, redundant and unnecessary. However, the agency's plan to incorporate Voluntary Self Inspection Programs (VSIP) into its inspection plan should be utilized whenever possible to maximize the agency's resources.

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

The current restrictions, which prohibit the importation of bovine-derived ingredients and live animals from countries with BSE, or those countries not engaged in appropriate surveillance activities, are adequate. The US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) is charged with preventing the importation of such materials into the United States. Manufacturers of pet food use only those imported proteins allowed by USDA. PFI urges the agency to continue its coordination with APHIS and other government agencies to prevent the importation of prohibited materials.

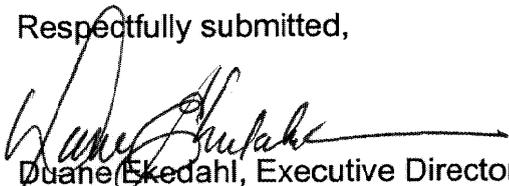
Pet Food Institute
Docket No. 01N-0423
November 20, 2001

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

The Pet Food Institute fully supports the current BSE-prevention efforts of the FDA and other federal agencies. At this time, all prudent measures to prevent the introduction and spread of BSE into the United States are in place. Only through further education and strict and full enforcement of the current regulation can the agency achieve its goal of 100 percent compliance with the current rule.

In conclusion, the members of the Pet Food Institute believe the feed restrictions contained in 21 CFR §589.2000 provides the necessary animal and human health protections and should not be changed at this time.

Respectfully submitted,


Duane Skedahl, Executive Director
Pet Food Institute

Express

FedEx

emp# 233441 20NOV01

TRK# 8278 8278 3164 FORM 0215

PRIORITY OVERNIGHT WED

Deliver By: 21NOV01 A2

20852 -MD-US

IAD 19 GAIA



154
1000

FedEx USA Airbill Express

FedEx Tracking Number

8278 8278 3164

0215

Recipient's Copy

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records.

Date 11/20/01 FedEx Tracking Number 827882783164

Sender's Name Duane Ekedahl Phone 202 367-1100

Company SMITH BUCKLIN & ASSOC

Address 2025 M ST NW STE 800 Dept./Floor/Suite/Room

City WASHINGTON State DC ZIP 20036

2 Your Internal Billing Reference PFI

3 To

Recipient's Name Food & Drug Administration Phone

Company Dockets Management Branch (HFA-305)
Animal Feed Rule Hearing

Address 5630 Fishers Lane, Room 1061 Dept./Floor/Suite/Room

City Rockville State MD ZIP 20852



0179441228

4a Express Package Service

FedEx Priority Overnight Next business morning

FedEx Standard Overnight Next business afternoon

FedEx First Overnight Earliest next business morning delivery to select locations

FedEx 2Day Second business day FedEx Envelope rate not available. Minimum charge: One-pound rate

FedEx Express Saver Third business day

NEW FedEx Extra Hours Later drop-off with next business afternoon delivery for select locations

4b Express Freight Service

FedEx 1Day Freight* Next business day

FedEx 2Day Freight Second business day

FedEx 3Day Freight Third business day

* Call for Confirmation

5 Packaging

FedEx Envelope*

FedEx Pak* Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak

Other Pkg. Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling

SATURDAY Delivery Available only for FedEx Priority Overnight and FedEx 2Day to select ZIP codes

SUNDAY Delivery Available only for FedEx Priority Overnight to select ZIP codes

HOLD Weekday at FedEx Location Not available with FedEx First Overnight

HOLD Saturday at FedEx Location Available only for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods?
One box must be checked.

No Yes As per attached Shipper's Declaration

Dry Ice Dry Ice, 9, UN1845 x kg

Cargo Aircraft Only

Dangerous Goods (incl. Dry Ice) cannot be shipped in FedEx packaging or with FedEx Extra Hours service.

7 Payment Bill to:

Sender Acct. No. in Section 1 will be billed.

Recipient Third Party Credit Card Obtain Recip. Acct. No. Cash/Check

Total Packages Total Weight Total Charges

Our liability is limited to \$100 unless you declare a higher value. See the FedEx Service Guide for details.

8 Release Signature Sign to authorize delivery without obtaining signature.

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims. Questions? Visit our Web site at fedex.com or call 1-800-Go-FedEx® (800)463-3339. SRS*Rev. Date: 12/00*Part #1859185*©1994-2000 FedEx*PRINTED IN U.S.A.

406