

APPMA[®]

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American Pet Products Manufacturers Association, Inc.[®]

November 21, 2001

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

Re: Submission of Comment on U.S. Food and Drug
Administration Notice "Substances Prohibited
From Use in Animal Food or Feed; Animal
Proteins Prohibited in Ruminant Feed";
Docket No. 01N-0423

Dear Sir or Madam:

The American Pet Products Manufacturers Association, Inc. (APPMA) is a trade association representing approximately 650 pet product manufacturers. Close to 40% of our members are small manufacturers, *i.e.*, with gross annual sales of less than \$500,000 nationally. We represent many larger manufacturers as well, with national distribution. Our industry employs more than 250,000 individuals in the manufacturing, distribution, and marketing of pet products, many of which include manufacturers who make pet food, widely considered to be the single most important product for the health and welfare of companion animals. A recent national survey conducted by APPMA shows that there are as many as 265 million pets in the United States (US) and that 61% of American households have at least one pet. Be they furry, feathered, or finned, Americans love their pets.

Transmissible Spongiform Encephalopathies (TSEs) including Bovine Spongiform Encephalopathy (BSE) are animal diseases, which have a devastating effect on animal and human populations alike. The introduction of BSE into the

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US would have a severe impact on many sectors of our economy. The US Department of Agriculture (USDA) Foreign Agricultural Service reports a 9% decline in European Union (EU) beef production due to consumer's waning faith in the safety of beef, as well as sluggish exports. In England, the outbreak reached crisis proportions, when consumers discovered that the government endorsed the safety of British beef, while hiding the fact that new cases continued to be diagnosed; resulting in an overall dissatisfaction with the government's ability to control the situation. Public perception that the food supply is not safe could lead to further devastating effects such as we are currently seeing in Japan's beef market, where, according to the U.S. Meat Export Federation, a recent single case of a BSE infected cow resulted in a chilling effect of such great magnitude that sales of beef in Japan fell by as much as 60%. Both the EU and Japan continue to study the problem and have enacted regulations intended to curtail the spread of the disease.

In order to prevent similar results in the United States, the US Food and Drug Administration (FDA), in 1997, enacted regulations intended to help prevent the introduction and spread of BSE through animal feed. The final rule, at 21 CFR 589.2000, prohibits the use of most mammalian protein in feeds for ruminant animals, as well as, sets specific labeling and record keeping requirements. To its credit, FDA set into place a policy that was comprehensive and based on scientific data and risk assessment. It engaged the various levels of the production industry through notice and comment and worked to educate the regulated community.

The rule is working. While other countries continue to discover BSE infection in cattle populations within their borders, the US remains BSE-free. As evidenced by recently published FDA surveillance reports, the vast majority of firms across the country are complying with the rule and as a result, not one case of BSE has been detected in the United States. According to a USDA risk assessment conducted in 1991, updated in 1996, and another conducted by the EU in 2000, the possibility that BSE exists in the United States is "unlikely". This is in large part due to the rules enacted in 1997, and the FDA's and USDA's efforts to educate and monitor the regulated community to safeguard the country's food supply at every level in the distribution chain.

FDA is now taking a prudent step by reviewing the rule and has asked the public for comment. We are grateful for this opportunity and wish to respond. First and foremost, we believe that the current rules are both fair and adequate to achieve the intended goal. The basic assumptions that underlie the original rule still exist. Any change in the law must be based on a thorough and well-organized risk assessment founded in sound science. Until there is scientific evidence to support a change in the law, education and rigorous enforcement of the current rule is the only measure that is recommended, based on a demonstrated success rate.

APPMA believes that additional bans, extended record keeping, or the elimination of exemptions do not and will not better achieve the mutual goal of government and industry, *i.e.*, to prevent the introduction and spread of BSE in the United States. Government and industry must become vigilant partners to assure that the introduction of BSE in the US will not occur. We believe that this is best achieved through ongoing surveillance and education of the regulated community, and not through additional regulation that does not appear to be warranted. Any additional regulation, which is not necessary, would make it more burdensome for the regulated community to comply with the existing regulations, which appear to be working.

Most important to the pet industry, we believe that there are no additional requirements that can be imposed on pet food that will not result in an enormous negative impact on the pet food industry, as well as, to companion animals. For instance, if the regulations were to require a warning statement on pet food, consumers are likely to become confused about the safety of feeding pet food to their beloved companion animals. We anticipate that FDA will consider APPMA's comments, in reaching any conclusion regarding modification of the regulations.

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

APPMA believes that the current rule has demonstrated success based on FDA's own reports regarding compliance. According to the FDA Center for Veterinary Medicine, as of October 26, 2001, a total of 10,018 firms have been inspected or re-inspected since 1997. Of this group, 333 firms (13%) were found to be out of compliance and re-inspection of these firms is already scheduled. An earlier report issued on July 6, 2001, showed that 22% of the total inspections conducted at the time were out of compliance. Significantly, to date, there has not been a single reported case of BSE in the United States. We believe that this disease does not exist in US cattle herds because of active monitoring and inspection of the animal feed industry. It is apparent that with increased inspections there will be a continued decrease in the levels of noncompliance.

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?*

APPMA believes that the current rule is not only adequate but has demonstrated its effectiveness in the 4 years since it was promulgated. The intended objective of the rule as stated in the notice is, "to prevent the establishment and amplification of BSE in the United States through feed." 62

Fed. Reg. 108, June 5, 1997, 30945. In addition, the rule is supported by industry efforts to educate itself as well as the monitoring activities of the USDA and the various state agencies involved in the inspection program. Consequently, we believe that the rule is meeting its objectives, and nothing need be added.

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 basic assumptions, which were the rationale for the promulgation of FDA's regulations in 1997 were based on scientific analysis, which has not changed. Without additional scientific reasoning, there is no justification to change the exemptions that exist.

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?*

Though we understand that FDA has detected some level of commingling due to noncompliance with the current rule, we believe that further enforcement will reduce the rate of noncompliance. Without a rational reason to believe that this measure will ensure against the introduction or spread of BSE, the cost of requiring all manufacturers to provide dedicated facilities for the production of feed would be unreasonable.

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

Without scientific evidence showing a correlation between this and contamination, there is no way to know whether the enormous expense would achieve the intended goal, *i.e.*, "to prevent the establishment and amplification of BSE in the United States through feed." 62 Fed. Reg. 108, June 5, 1997, 30935, 30945.

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?*

No. Licensing will not achieve the intent of the rule. Renderers are licensed at the state level, a fact that assisted FDA in identifying firms for inspection. Therefore, identification of facilities is not a problem. Rather, FDA should devote its resources to further education and inspections to better gauge compliance with the current rule. In this way, full compliance may be achieved.

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)?*

No. Our position is that the current rule is adequate to achieve the intended goal of eliminating the risk of the introduction of BSE into the US.

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?*

No. Without a scientific rationale for concern about the safety of poultry litter or other recycled waste products, there is no reason to change the rule. To date, there is no evidence to link TSE agents in poultry populations.

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

Mammalian protein is an essential source of nutrition needed for a complete and balanced diet for many companion animals. It is used by a significant number of pet food manufacturers in their formulations. Consumers must feel confident that they can continue to serve their precious pets, well-balanced food.

Companion animals come in all shapes and sizes and so do pet food packages. FDA recognizes a host of pet animals including dogs, cats, rats, mice, hamsters, gerbils, rabbits, ferrets, nonhuman primates, canaries, psittacine birds, mynahs, finches, tropical fish, goldfish, snakes, and turtles. Pet food is sold in smaller packages and at higher prices than traditional ruminant feeds, and therefore is not likely to be incorporated into ruminant feeds. If pet foods for these various animals were labeled, "not for use in ruminants," it is beyond a doubt that many consumers would be confused and become skeptical about the nature of what they are feeding their pets. This confusion could lead consumers to feed their pets inappropriate formulations.

Should pet food require such a label, consumers may wrongly conclude that it is a common practice to feed pet food to cattle and other ruminants. In fact, under the rules, salvage or distressed pet food, packaged in bulk, is required to be labeled to warn against ruminant feeding. We believe that it is extremely uncommon for pet food to be fed to ruminants and that the existing labeling requirements are sufficient to assure that pet food will not be fed to ruminants.

In 1997, FDA appropriately stated that there is no need for this kind of alarm. Given that the risk is extremely low, requiring a cautionary statement on pet food labels would do much more harm than good; as it would confuse the consumer and add an unwarranted burden on the pet food industry. A more

appropriate response to the negligible risk of feeding ruminants pet food is to actively enforce the current regulations to ensure full compliance.

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

No. Extension of the current one-year recordkeeping requirement will result in more records without a clear function.

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".*

Collective terms is a standard endorsed by the Association of American Feed Control Officials and widely accepted by industry. Changing this rule would cause an unnecessary burden on industry without a clear benefit.

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?"*

While consumers do not have a clear understanding of the cautionary statement relating to ruminants, farmers do. There is no rational reason to change the language of the cautionary statement, thereby, requiring different labels to be printed when the target audience has an adequate understanding of the current label language. Changing the language of the cautionary statement is an unnecessary variation.

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?*

This question requires a scientific perspective that we are not able to provide at this time. However, the basic assumptions provided by FDA in 1997 are still true today. In the past, European farmers fed protein derived from animals to ruminants. These protein products contained TSEs, which could be transmitted to ruminant animals. In the United Kingdom, epidemiologic evidence suggested a correlation between an outbreak of BSE in cattle fed a diet of protein derived from sheep infected with scrapie, another TSE. This outbreak was then linked to human illness from new variant Creutzfeldt-Jakob disease (nv-CJD) reported in England. Though BSE has never been detected in the United States, FDA promulgated these regulations "intended to prevent the establishment and amplification of BSE in the United States through feed and thereby minimize any risk to animals and humans." 62 Fed. Reg. 108, June

5, 1997, 30935. We strongly support this action based on the facts then and now.

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?)*

FDA has used its inspection authority in cooperation with state agencies across the country. This joint effort has resulted in the inspection of over 10,000 firms. After re-inspection, 90% percent of inspected facilities are in full compliance with the regulations. In the meantime, President Bush has proposed a \$35 million supplemental appropriation for surveillance including \$8 million to shore up the federal and state surveillance infrastructure. With more inspectors, FDA can achieve its goal on full compliance with the current law.

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

APPMA maintains that the current regulations coupled with FDA's enforcement activities, are the most important factors to keep the US food supply BSE-free. Certification programs that have developed to assist feed mills, renderers and manufacturers are acting as an educational tool to spread the word about the importance of compliance. These programs help the regulated community examine itself and implement plans that will ensure full regulatory compliance.

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

Import restrictions which were implemented in an emergency rule in December 2000 and later finalized by USDA in an interim rule this summer, have had a very severe impact on the pet product industry. A dog supplement company owned by an APPMA failed due to the inability to import its supply of bone meal. Another member reported cancellation of launching a new small animal treat due to import problems. For many fish food manufacturers, this has been a trying period, in which importers faced months of uncertainty and later dealt with complicated criteria for release of their product. Nonetheless, our members are complying with these changes and APPMA supports the USDA's policies. We hope that FDA will work with USDA, and their joint efforts will encourage a free flow of communication and accordingly, a speedy response to industry's request to be given clear guidance on how to legally import pet products into the United States.

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

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We reiterate our position that the current firewalls in place are adequately protecting the US cattle population from introduction of the BSE agent. These include the FDA ruminant feed rule and comprehensive inspection program as well as efforts on the part of USDA, various state agencies, and trade associations. Consequently, we envision no other requirements that are necessary to achieve the goal.

We respectfully submit our views.

Sincerely yours,

A handwritten signature in cursive script that reads "Gina Valeri".

Gina Valeri

Director of Legislative Affairs & General Counsel

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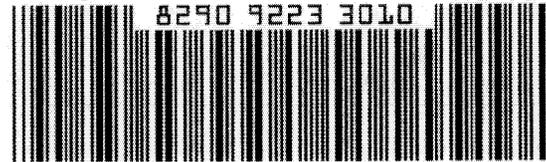
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