



PET FOOD INSTITUTE

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April 29, 2004

VIA FACSIMILE and email

Stephen F. Sundlof, DVM., Ph.D.
Director
CVM/FDA
7519 Standish Place, HVF-1
Rockville, Maryland 20855-0001

Re: Prohibition of SRMs from Animal Feed

Dear Dr. Sundlof:

I am writing on behalf of the members of Pet Food Institute ("PFI") regarding our belief that it is legal for the Food and Drug Administration, Center for Veterinary Medicine to take further action regarding the removal of certain animal parts from animal feed.

In January 2004, the Food Safety and Inspection Service ("FSIS") designated certain body parts of cattle as "specified risk materials" ("SRMs") and declared that these materials are inedible and prohibited for use in human food. FSIS enacted this ban in order to minimize human exposure to materials that current science has demonstrated are the most likely to contain the bovine spongiform encephalopathy ("BSE") agent in cattle infected with the disease. CVM is now considering whether to ban SRMs from animal feed.

In order to make the food and feed supplies as safe as possible following the detection of a BSE-positive cow within our borders, PFI believes CVM should prohibit SRMs from all animal feed and urges the Center to do so immediately. Although the current state of the science appears to demonstrate that certain animals, such as porcine and avian species, do not

amplify the BSE agent even if they ingest it and do not themselves appear to be susceptible to contracting the disease (“non-susceptible species”), science has not ruled out the possibility that these species could pass on the disease agent in their tissues. If these animals were to ingest SRMs from a BSE-infected cow and harbor the infective agent within their tissues, and if that infective agent were to be ingested by a susceptible species, such as a ruminant or human, the possibility does exist that the susceptible species could contract the disease. As such, the tissues of such “non-susceptible” animals having ingested infective SRMs, when those tissues are used as food or feed ingredients, would be adulterated under Section 402(a)(1), (a)(2)(A) or (a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (“the Act”) (21 U.S.C. §342(a)(1), (a)(2)(A) or (a)(2)(C)) as containing a deleterious substance that may render the feed material injurious to health, an added deleterious substance or an unsafe food or feed additive. Feed materials that could cause such adulteration, i.e., infective SRMs, would also be adulterated under Section 402(a)(1). CVM has the power to prohibit the inclusion of SRMs in animal feed under its general powers pursuant to the Act. The simplest potential mechanism to regulate these adulterating products is to amend 21 C.F.R. Part 589 to prohibit the use of SRMs in animal feed.

Additionally, SRMs could be regulated as feed additives under the 1958 Food Additives Amendment. Feed additives must be shown to be safe before they are permitted to be used in food or feed. SRMs that may be infective clearly cannot be generally recognized as safe. Indeed, FSIS has already so concluded when it removed SRMs from human food.

Significantly, CVM has the power to declare SRMs to be adulterated or to be feed additives that are not GRAS for use in animal feed, or to declare adulterated the food or feed in which they are incorporated, before any actual harm occurs. In the preamble to the Federal Register Notice publishing the final version of Section 589.2000, CVM noted that the Act does not require that FDA wait until actual harm occurs before declaring a substance to be non- GRAS.¹ All that is required is information “that the use of [a particular substance in] feed may not be safe or that there is no expert consensus that the use of the substance is

¹ 62 Fed. Reg. 30936, 30949 (June 5, 1997).

safe.”² Thus, CVM may use the Act as a whole, including the 1958 Food Additives Amendment, as a tool to prevent harm to the public health before it occurs.³ In the final ruminant feed ban rule, for example, FDA concluded that a consensus did not exist that the use of protein derived from mammalian tissues is safe for use in ruminant feed.⁴

Whichever mechanism CVM chooses to use, the Center should affirmatively increase the safety of the food and feed supply by prohibiting inclusion of possibly infective SRMs in the food or feed chains. Because science cannot definitively rule out the possibility that infective material could be passed to susceptible individuals, such as ruminants or humans, by ingestion of “non-susceptible” animals who have themselves ingested SRMs, inclusion of SRMs in animal feed renders the feed and the tissue of the animals ingesting that feed, when the tissue is later incorporated into food or feed, adulterated. Additionally, SRMs are non-GRAS for use as food or feed additives.

We believe that CVM should exercise its abundant current authority to under the Act to ban these substances from animal feed. Thanks for again allowing Pet Food Institute to comment on this issue.

Sincerely,



Nancy K. Cook
Vice President
Technical and Regulatory Affairs

cc: Dr. Lester Crawford, Acting Commissioner, Food and Drug Administration

² *Id.*

³ *Id.* (citing *United States v. Ewig Bros. Co.*, 502 F.2d 715, 721 & n.24 (7th Cir. 1974), *cert. denied*, 420 U.S. 945 (1975); S. Rep. No. 2422, 85th Cong., 2d Sess. 1-3 (1958); H.R. Rep. No. 2284, 85th Cong., 2d Sess. 1 (1958)).

⁴ *Id.*