



660 PENNSYLVANIA AVE., SE , SUITE 302, WASHINGTON, DC 20003
(202) 547-9359 • FAX (202) 547-9429
1009 GENERAL KENNEDY AVE., #2 SAN FRANCISCO, CA 94129
(415) 561-2524 • FAX (415) 561-7651
WWW.CENTERFORFOODSAFETY.ORG

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2004N-0264 (RIN No. 0910-AF46)

To Whom It May Concern:

The Center for Food Safety (CFS) submits these comments pursuant to the joint USDA/APHIS and FDA advanced notice for proposed rulemaking (ANPRM) entitled “Federal Measures to Mitigate BSE Risks: Consideration of Further Action” contained at 69 Federal Register 42288 (July 14, 2004).¹

I. FDA Has Unreasonably Delayed in Making Regulatory Changes to 21 C.F.R. §589.2000.

On January 7, 1999, CFS, along with the Humane Farming Association, Center for Media and Democracy and affected individuals, submitted a petition for rulemaking that requested the FDA to amend 21 C.F.R. § 589.2000 to include a number of actions discussed in the FDA’s ANPRM. The petition request, inter alia, the FDA take the following steps to amend the definition of “protein derived from mammalian tissues” so as to: (1) ban use of blood and blood products in all animal feeds; (2) ban the use of gelatin in all animal feeds; (3) ban the use of all porcine materials in all animal feeds; and (4) to amend labeling of animal feeds consistent with the request. In accordance with FDA regulations, the petition was supported by numerous scientific and other documents. These materials and numerous

¹ CFS delay in filing of these comments were the result of the joint nature of the USDA/FDA’s notice provided in the Federal Register. Given the lead nature of USDA/APHIS in the titled of the ANPRM, CFS interpreted the notice incorrectly and believed the date for submission of all comments to be September 13, 2004 and not August 13, 2004 to FDA.

public comments in support of the petition are contained at FDA Docket No. 99P-0033.

Despite having a regulatory obligation to respond within 180 days, to date FDA has failed to answer the CFS petition. See 21 C.F.R. § 10.30(e)(2). FDA is in receipt of letters apprising the agency that its failure to respond to the petition constitutes unreasonable delay - letters dated August 5, 1999; and May 8, 2000. Furthermore, on November 6, 2002, the FDA sought information concerning use of SRMs in animal feed, poultry litter, use of pet food and plate waste. 67 Fed. Reg. 67572 (Nov 6, 2002). The agency took no further steps after the publication of the 2002 ANPRM.

On January 26, 2004, FDA announced that it would institute ban on blood products, poultry litter, plate waste as an interim final rule. HHS Press Release, Expanded “Mad Cow” Safeguards Announced to Strengthen Existing Firewalls Against BSE Transmission (Jan. 26, 2004). The agency’s use of another ANPRM, however, exemplifies continued FDA delay in addressing the critical consumer and animal health issues raise by loopholes in the existing feed regulation. Scientific material submitted in response to the questions presented by the FDA in its new ANPRM have been submitted to the agency on numerous occasions including supporting material to the CFS petition and comment responses to the 2002 ANPRM. Indeed, the agency appears to use the new International Review Team (IRT) report, released only seven days after its January announcement, as a means to further delay instead of taking the preventative actions supports by the IRT. To that end, the FDA’s action in issuing another ANPRM is negligent and constitutes further unreasonable delay. CFS believes its requests in 1999 petition remain germane as does material filed with that request, and CFS again requests that its 1999 petition be answered in the affirmative.

II. Legal Authority of FDA

FDA also seems to be suggesting that it now does not view it has legal authority to amend the current feed regulation in a manner necessary to adequately prevention future occurrences of BSE. In question 30, the FDA asks whether the potential for cross contamination of ruminant animal feed with non-ruminant animal feed containing specified risk materials (SRMs) provides a legal basis for ban the of SRMs and other cattle material in non-ruminant feed? CFS believes the answer to question 30 is yes for several reasons.

First, material supporting the CFS petition and numerous other comments received by the agency in response to past BSE feed regulatory proposals and notices support that transmissible spongiform encephalopathies (TSEs) cross numerous species boundaries - this science has not changed. The agency should act to prevent future infection of all U.S. animal populations from TSE infectivity and to that end SRMs should not be used in any animal feed.

Second, in 1997, the FDA asserted that “protein derived from mammalian tissues” are food additives. The definition of “protein derived from mammalian tissue” excludes several things, such as blood, and plate waste, now being considered for inclusion in the definition. See 62 Fed Reg 30935, 30962 (June 5, 1997). The FFDCA defines food additive as “any substance the intended use of which results or may reasonably be expected to result , directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . .” 21 U.S.C. § 321(s). The IRT report makes it quite clear that the even the intended use of SRMs and other cattle material in feeds for non-ruminant animal creates a situation (on-the- farm or elsewhere) in which it is reasonably be expected to result in such feed becoming directly (through co-mingling) or indirectly (through production contamination)

a component of ruminant feed. IRT report at 8-9. The bottom line of the IRT report is that if the country produces animal feed containing SRMs, regardless of its primary feed target, it will contaminate and adulterate ruminant feeds. FDA's own surveys of compliance with the 1997 feed rule indicate this - even the recent July 29, 2004 survey. See also, FDA/CVM Feed Ban Inspection and Compliance Update (2001); GAO, "Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts (Jan. 2002). The 2004 survey exemplifies that contamination and mix ups do occur. As a result, the FFDCA (and the FDA's own legal basis for the 1997 regulation) provides authority for the agency to ban the use of SRMs and all meat and bone meal (including avian) from use in ruminants, and CFS encourages the agency to do so.

In sum, it is time for FDA to stop its delay tactics and to amend the feed rule so that it provides maximum protection against the introduction and amplification of BSE into the U.S. food supply.

On behalf of CFS,

/s/

Joseph Mendelson III
Legal Director