CENTER FOR BIOSECURITY, FOOD SAFETY, & PUBLIC HEALTH

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Dear Sir or Madam:

PREAMBLE/INTRODUCTION

The Center for Biosecurity, Food Safety and Public Health (CBFSPH) is a registered corporation in the State of Florida, intent on promoting the principles of biosecurity, food safety, and public health protection. A part of the Center's mission is to serve as a resource to address the policy issues associated with safe food production. As a result, we take this opportunity to submit comments/answers to the questions/concerns proposed in your advance notice of proposed rulemaking. The Center hopes that it can be an objective and responsible voice for the continued progression of animal agriculture in North America, while assisting food-producing industries in the continued manufacture and commercialization of safe food, and the regulatory agencies in the promotion of scientific affirmation in decision making.

This, therefore, references Docket No. 02N-0273, an Advance Notice of Proposed Rulemaking (ANPR), in which the agency is soliciting information, comments and opinions on some potential changes to its current rule: "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" with special pertinence to five specific questions. The intent of the agency is to improve the rule and its enforcement to prevent the establishment and amplification of bovine spongiform encephalopathy (BSE) in the United States, the nucleus of the existing rule.

A very interesting statement to amplify the rationale of potential modifications to the current rule was made in the second sentence of the summary needs further explanation and defining by the agency: "We put this regulation in place to prevent the spread through animal feed of the agent of bovine spongiform encephalopathy (BSE) were it to enter the United States." We are not aware that the infectious agent (presumably a prion) of BSE has entered the United States. At present, the disease is a foreign animal disease with incidence of close to 99 percent in the United Kingdom (U.K.) where the disease was first

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diagnosed in 1986, and the other approximate 1 percent involves countries in Europe contiguous to the U.K. and others like Japan that either imported contaminated animal protein or live cattle from the locus of the origin of BSE.

All the official epidemiological determinants including extensive surveillance and testing of high-risk animals indicate the disease (BSE) does not exist in the United States. Even the General Accounting Office (GAO) in its report to Congressional requesters indicated: "No cases of BSE-infected animals have been detected in the United States (1)." Equally pertinent, we are also not privy to any information in the annals of regulatory medicine in the United States that would indicate any regulation was ever written to institute preventive controls without the disease being present in the country. The exception is BSE and one could surmise because the infectious agent is definitely non-conventional, but interestingly, with very defined limits of infectivity. In essence, also, we have already exceeded the factors normally considered prudent by international disease control authorities in formatting not only a regulation, but also policies/directives as early as 1987 by the lead responsible government agencies that will prevent "the establishment and amplification" of the infectious agent of BSE in the United States.

BACKGROUND

On October 30, 2001, the Center for Veterinary Medicine (CVM) of the Food and Drug Administration (FDA) invited comments on 17 questions about the "ways and means" to improve enforcement to prevent BSE from entering the United States. Many organizations took the time to judiciously prepare written and oral comments to achieve that objective. In reality, it was a distinct cooperative outreach by those involved to assist the agency in its quest to examine the varied issues of the subject and evaluate options.

Like all public hearings, everyone had an opportunity to be fully expressive and heighten their concerns and opinions on the diverse issues. Indications from that meeting were that the overwhelming consensus was that the present feed rule was adequate and appears to be working well and meets the objectives of the agency. The questions posed, although a good resource to assist the agency to assess the prevailing public sentiments, the status quo should persist, since there was no apparent change in the original risk factors, nor were there any reasons to speculate that new findings would cause a need to modify any aspect of the current rule. A logical assumption would be that the agency took the written and oral comments seriously since the agency hosted the hearing and was operating with the objective to be fair in the

examination of the testimonies presented. A summary of the agency's interpretation of the comments made during the proceedings should be made available for public scrutiny, including any statements made (written or oral) that would influence the agency to consider modifying aspects/concepts of the present rule.

The agency rightly referenced the Harvard Center for Risk Analysis findings and report released on November 26, 2001, that evaluated over a three year period the various risks and potential pathways for exposure of U.S. cattle to the BSE agent. The mathematical model (likely the most comprehensive ever used to assess the relevance of an animal disease to public health) applied by the Harvard epidemiologists concluded that, due to the control measures already in place, the risk to U.S. cattle and to U.S. consumers from BSE is very low. Actually, a direct quote from the executive summary should provide comfort to FDA: "Our analysis finds that the U.S. is highly resistant to any introduction of BSE or a similar disease. BSE is extremely unlikely to become established in the U.S." (2). In the language of epidemiology, and the subsequent assessment of the likelihood of a cause–effect relationship, the afore-mentioned statements are very strong and meant to highlight a conviction in the findings that while elements of minute risk might exist, as would be expected in any infectious process, risk factors are not present to cause "the establishment or amplification" of the infectious agent in the United States. In reality, our instituted preventive controls have worked well to limit pathways for the transmission of the infectious agent had it been present in the United States.

While, as an industry, we commend the government's proactive and preventive approach, the success of our country's control initiatives was a clear demonstration of all involved sectors working together interactively to keep this enigmatic disease with its public health implications from gaining a foothold in the United States. Logically, we have been doing this for about 16 years, and currently, with all the instituted controls, we can all safely say that the country has the lowest level of potential risk factors since 1986 for an outbreak of BSE. It is a fact that should be celebrated, not be perpetuated with constant doubts and lingering concerns that we have not done enough to eliminate every potential pathway of the disease. We have a story of success, why taint it with the taunts of uncertainty!

AGENCY REQUEST FOR INFORMATION

1. Excluding Brain and Spinal Cord From Rendered Animal Products

The agency should totally decouple any inference to what the Food Safety and Inspection Service (FSIS) is considering relative the use of tissue of the central nervous system from specified cattle (brain and spinal cord), considered "high-risk," from use in human food. It is an additional possible regulatory action the agency (FSIS) may take to limit the risk of human exposure to BSE. The agency has stated in its thinking paper "that BSE has not been detected in the United States" (3). The relative risk for comparative assessment and analogy of FSIS' possible policy adoption to rendered animal proteins regulated by the agency does not exist. Each agency has to determine risk factors and subsequent policies based on the risk as assessed and the subsequent pertinence to its mission/responsibilities. To posture that because FSIS may use possible precautionary measures to limit human exposure to "high-risk" tissue does not automatically apply to same tissues that are further processed into feed ingredients. Even the "precautionary principle" stretched to parallel zero risk has limits.

The Food Safety and Inspection Service (FSIS) proposal to examine the issue of inclusion of brain, spinal cord, or fragments of nerve tissue from the food chain in advanced meat recovery (AMR) processing is that inclusion of these tissues can be considered "foreign material" in meat products and a labeling violation could be implied. Other regulatory factions, concerned about the public health implications of BSE in countries with the disease, want to introduce controls based on public health protection. But, the important consideration should be that we do not have BSE in the U.S. and have used brains from different animal species for at least 100 years in the food chain without adverse health consequences. The decision, therefore, for use of these tissues as food should be a choice for consumers, unless there is proven evidence that the disease does exist in the country. Government should not regulate in an environment of disparity. We proclaim in official documents/pronouncements that the country is free of BSE, and we attempt to promulgate rules as though the disease does exist in the country. We are sending confusing messages and in the process disenfranchising the industries who have collaborated and cooperated with government to make our country BSE-free.

In similar context, we have the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture USDA), making concerted efforts to convince the European Union (EU) and the international world of commerce that the country is free of BSE and should be able to ship meat products originating from cattle without any consideration for the removal of specified risk material (SRM) e.g. brain, spinal cord etc. This carries over into the rendering industry where we do not think that it is necessary to exclude SRMs from the rendering "stream" unless BSE exists in the country. Also, the reason

why renderers are especially concerned about the comparative with the FSIS' proposal is that the SRMs will be subjected to further processing at rendering temperatures that will inactivate the infectious agent to a marked degree, albeit, not completely. An important reminder is that rendering methods anywhere in the world have never been capable of completely inactivating any of the infectious agents that are associated with the transmissible spongiform encephalopathies TSEs). But, the deciding factor is that BSE, the only known TSE considered zoonotic (transmissible to man) is absent from the country, and restrictions over and above the working controls currently in place should not be a considerate option.

Equally pertinent, our government is busy working to attain a classification of our country into category I by the different classifying bodies e.g. the European Union and the Office Internationale des Epizooties (OIE) in Paris that will permit the U.S. the option of not having to remove SRMs from the rendering stream because of the absence of BSE in the country. This initiative should be supported collectively by our government agencies without introducing the nuances of doubt about our BSE status by sending confusing signals.

Obviously, any exclusion of material that can be safely processed should be based on science and not the current political whims to address the extremes of precaution. We have a current rule that protects animal and human health and any likelihood of transmission of the infectious agent. Removal of SRMs would involve unnecessary costs, necessitate a dramatic restructuring of facilities and result in a severe negative impact on small family owned rendering facilities, some with possible closure, without providing the concurrent benefits of pubic health protection.

The bottom line should be, is anything more needed over and above the existing rule that currently demonstrates the agency's objectives are met through compliance findings of 99% plus! This should be a reason to posture, instead of the agency's decision makers wondering and pondering whether or not they have instituted enough controls as a government. The existing rule that you are attempting to modify or addend is working and compliance affirms it. Interestingly, the risks identified in the initial rule that heightened the rationale for the action taken by the agency are convincingly lower in this country than at any time since BSE was first diagnosed in the United Kingdom in 1986.

2. Use of Poultry Litter in Cattle Feed

The Harvard risk assessment indicated that the risk (?) from the use of poultry litter as a feed supplement for cattle should be investigated further. Obviously, the agency is concerned that spilled feed in poultry houses could contain meat and bone meal (MBM) of ruminant origin and begs the question whether this practice would constitute a significant break in the feed regulations?

It should be a logical assumption that if Harvard epidemiologists/risk analysts, after a three-year assessment of variable risk factors associated with the pathways of transmission of BSE, considered poultry litter a viable and meaningful element of risk and could "represent a significant break in the feed regulations" that they would have evaluated the relevance in more depth and with degrees of concern. The mere fact that they did not delve further into the subject is an indication of the limited significance, and the multitude of unknowns needed to determine with any degree of pertinence or certainty, the "hazard" associated with the practice. The evaluation of the amount of feed spillage in the litter could vary widely from facility to facility, the varying methods used by producers in processing the litter prior to inclusion in feed, and any attempts to develop a generic model that would be applicable toward a logical conclusion of risk linkage associated with possible spillage and subsequent use would defy the most ingenious minds.

CVM as early as June 14, 1998, made policy statements on this subject and implied that litter/manure can be fed to ruminants: "FDA has no evidence that the agent that causes BSE would survive the chicken intestinal tract." It was a reasonably rational statement at the time, and in spite of the continuing anxiety associated with this unconventional infectious agent, it remains a logical statement to this day. The agency to its credit realizes that litter/manure may contain a small amount of poultry feed, and that commercial poultry production takes measures to limit and control spillage.

Worst-case scenario theories were used to assess any likely risk associated with the feeding of poultry litter to ruminants. The calculations used two different mechanisms that resulted in close to identical numbers (0.23% - 0.28%) ruminant protein in poultry litter, based on assumptions that all animal proteins utilized in poultry rations are of ruminant origin, which obviously they are not. It has been calculated that approximately 1% of all poultry litter generated is fed to ruminants in the United States (4,5).

(1)

8 billion broilers produced per year

9 lbs. feed/broiler

5% ruminant protein in broiler rations

1% feed transition from feeder to litter

2 lbs. litter/broiler
(8,000,000,000 broilers/year x 9 lbs feed/broiler) = 72,000,000,000 lbs. feed/year

(72,000,000,000 lbs. feed/year) x (5% ruminant protein)
x (1% transitioned) = 36,000,000 lbs. annual protein/year

(8,000,000,000 broilers/year) x (2 lbs. litter/broiler) =
16,000,000,000 lbs. litter/year

(36,000,000 lbs. animal protein/year/(16,000,000,000
lbs. litter/year) x (100) = 0.23% animal protein in the
litter. (4)

(2)

Weight gain per bird - 5 lbs.
Lbs. feed/lb. gain - 1.8
Birds per turn – 25,000
Weeks per turn – 7
Feed transitioned from feeder to litter – 1.00% (Dale Univ. of
Georgia)
Maximum amount of animal protein in ration – 5.00%
Animal protein is 100% ruminant
Litter volume – 10,000 cubic feet (500 ft x 40 ft x ½ ft)
Litter density – 30 lbs/cubic ft.
Litter clean out schedule – (1) after each turn or (2) once per year

Clean Out Schedule (1) – after each turn

(5 lbs gain) x (1.8 lbs feed/lb gain) x (25,000 birds/turn) = 225,000 lbs feed/turn

(225,000 lbs feed) x (1.00% transitioned) x (5.00% animal protein) = 112.5 lbs animal protein

(112.5 lbs animal protein)/300,112.5 lbs and animal protein) x (100) = 0.037% animal protein in the litter

Clean Out Schedule (2) – once per year

(52 weeks/yr)/(7 weeks/turn) – 7.43 turn/year

(225,000 lbs feed/turn) x (7.43 turns/year) = 1, 671, 750 lbs feed/year

(1,671,750 lbs feed) x (1.00% transitioned) x (5.00% animal protein = 835.88 lbs animal protein

(835.88 lbs animal protein)/(300,835.88 lbs litter and animal protein) x (100) = 0.28% animal protein in the litter. (4)

The use of poultry litter in cattle feed in the country is limited by geography, difficult to fully assess, close to impossible to adequately regulate, and a practice so small in occurrence that attempts to formalize it into a regulatory context just does not make sense. In a free society like the United States, nonetheless, unless risk, which really parallels the impossible to determine in this case, the banning of the practice would be arbitrary and devoid of any scientific validation/affirmation for doing so.

3. Use of Pet Food In Ruminant Feed

Under 589.2000 (d) (4), the agency took all the necessary precautions to preclude the potentiality for distressed or salvaged pet food items by requiring the label requirements of: "Do not feed to cattle or other ruminants." That was both logical and forward thinking despite the limited risk for transmission of the infectious agent through this medium. There is absolutely no scientific rationale to modify in any way the exclusion for cautionary labeling on pet food sold at retail.

I see no positive impacts, other than to possibly appease a zero risk advocate (s). And, the unnecessary economic impact could have severe negative consequences on pet food manufacturers. In essence, format regulations that will provide the industry every incentive to work with the agency as collaborating partners. Make them feel a part of the cycle of food safety instead of promoting barriers devoid of generally considered accepted risks, even in a country without BSE!

4. Preventing Cross Contamination

The agency referenced the Harvard's risk assessment and the public hearing in Kansas City, MO. as sources of concern to re-examine the subject of cross-contamination as a possible BSE risk. The current rule mandates firms handling prohibited and non-prohibited material to have a written plan in place to prevent cross-contamination.

The agency again must be commended and take credit for the many joint meetings and teleconferences conducted with the rendering and feed industries to highlight the aspects of the rule that needed clarification and further elucidation. These joint endeavors were positive and provided an environment to share information readily and clarify doubts. They were definitely educational and played a definite role in contributing to the current high level of compliance with the rule, currently over 99%. This was reinforced by the agency's comprehensive compliance guides, and on site advice/suggestions during inspection audits. In reality, it was a meaningful government-industry relationship to attain compliance with the rule. This was further supplemented by the industry's own third part compliance auditors who were there not only to determine compliance with the rule based on FDA's elements, but to educate the industry on other factors of compliance protocol and food safety.

The rendering industry has already instituted the established controls and measures in writing and practice to prevent commingling as defined in the rule and in the compliance guidelines – sequencing, flushing, and the use of dedicated equipment. This is a subject that can be referenced by the industry's own third party and FDA's own compliance findings.

The agency made a suggestive inference to absolute surety for preventing potential carry over or cross-contamination. To reiterate, this has already been done by the industry (refer to aforementioned comments). Other preventive measures in the rule would also serve as a form of back up assurance e.g. the labeling requirement – "Do not feed to cattle or other ruminants." In reality, the rule is so multi-dimensional that per chance there is ever a violation of one aspect of the rule, other prevailing factors would predominate and prevent any likelihood of transmission of the infectious agent.

5. Elimination of the Plate Waste Exemption

This was a definite surprise, bordering on astonishment, that the plate waste issue would resurface in deliberations to determine whether this current exemption to the rule should be reconsidered. Plate waste is "food products that have been inspected by the FSIS or an equivalent state agency, and presented for human consumption" (2).

There are approximately 6 processors of plate waste in the country, and bakery products comprise approximately 90% of all plate waste going to animal feed. In essence, the "waste" is predominantly non-meat products and it has been determined that infective tissues of ruminant origin are extremely unlikely to be included in plate waste. A conclusion in the Harvard risk assessment states: "Plate waste consists of little mammalian protein, and the tissues that are included in this waste are unlikely to contain BSE infectivity. Moreover, plate waste undergoes a substantial amount of heat treatment, which would further reduce the level of infectivity in this material" (2).

The thought that this exemption could be even reconsidered is disconcerting from many perspectives: we are talking about inspected meat products that have been passed for human consumption by agencies of the U. S. government; we are considering products that have been on the plates of American consumers and were "leftovers;" we are reexamining options for products with less than "microscopic" risk in a worst case scenario analysis, in a country that the responsible government agencies consider free of BSE, based on government administered testing and surveillance programs; and last but also important, we are assessing products that will be further heat-processed to a degree that would eliminate an infectious titer capable to transmit disease.

The questions that were posed in the ANPR with emphasis on plate waste have been addressed in the aforementioned comments, plus the fact that the subsequent use in ruminant feed is so minimal that a quantitative assessment of risk is impossible. Equally problematic

would be the complete inability for exposure analysts to assess any likelihood of a cause – effect relationship, making the analogy and the significance moot.

SUMMARY

BSE, like most neuro-degenerative diseases is enigmatic and complex and CBFSPH complements the agency for its pursuance in the re-examination of various issues relating to the animal protein feed prohibition with relevance to the control and prevention of the disease and elimination of its human health implications/consequences (6). A retrospective consideration of the subject, including the current advance notice of proposed rulemaking (ANPR) and the requests for comments to the questions posed, CBFSPH, nonetheless, feels that approximately 6 years since the rule has been in place, the process is working well based on official compliance findings of the agency, and the rendering industry's own third party audits. CBFSPH and the industry recommits its resources to work diligently with the agency to ensure continuing compliance, but sees no need for any modifications or changes of the current rule unless well-established new risk factors validated by science, and devoid of the traditional anecdotes, are clearly identified that will dictate otherwise. In fact, change will send a message of continued uncertainty in our country, about 17 years after the disease was originally diagnosed in Great Britain, and still no evidence of it in this country. With the instituted preventive controls since 1987, and a rule in place since 1997, there is a time for closure, and a continuation of the policies that have worked to this day to keep the disease out of this country.

Should anyone care to discuss any of the issues outlined in this response to the docket, please feel free to do so by using any option (phone, FAX or e-mail) from the Center's stationary.

Sincerely,

Don A. Franco

Don A. Franco, DVM, MPH, DVPM
President

REFERENCES:

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2. Harvard Center for Risk Analysis: Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States: A Report to the Department of Agriculture, November 26, 2001.

3. Food Safety and Inspection Service (FSIS): Current Thinking On Measures That Could Be Implemented To Minimize Human Exposure To Materials That Could Potentially Contain The Bovine Spongiform Encephalopathy Agent. The Federal Register, January 17, 2002.

4. Custer, K.: Chairman, Animal Protein Producers Industry. Consultations on the subject with Dale, N. (University of Georgia) – Personal Communication.

5. Mc Caskey, T: Microbiologist, Auburn University. – Personal Communication.

6. Franco, D.A.: Controls in place to prevent transmission of BSE. Feedstuffs. Volume 73, No. 7, February 12, 2001.