NORTH AMERICAN RENDERING INDUSTRY

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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:

This references Docket No. 01N-0423, and the agency's solicitation for information and views on the current rule, "Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed" with special pertinence to the public hearing and subsequent request for comments as published in the Federal Register, October 5, 2001 (Volume 66, Number 194).

The relevance of the request for comments is basically a determination on whether the present "animal feeding regulation" with the purpose to help prevent the establishment and amplification of the agent (s) of bovine spongiform encephalopathy (BSE) in the U.S. cattle herd through feed and thus minimize any risk to animal and human health from such agent (s), and, in the process, a concurrent determination and assessment of the effectiveness of the final rule, 21 CFR, 589.2000 (Federal Register, June 5, 1997).

Submitted comments reflect the current thinking and recommendation of the North American Rendering Industry (NARI) standing committee on the transmissible spongiform encephalopathies (TSEs). NARI is a cross-representation of the three major rendering organizations in the country, the National Renderers Association (NRA), the Animal Protein Producers Industry (APPI), and the Fats and Proteins Research Foundation (FPRF).

The questions posed by the agency are broad-based and comprehensive and vary from the major aspects of public health and environmental concerns, to concepts of animal feed with pertinence to the human food supply, to elements of economic modifications and impact to the industry at large.

NARI's committee on the TSEs plan to address the questions in the chronological order as represented in the Federal Register, Volume 66, Number 194, October 5, 2001.

1. What 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?

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The agency must be reminded at the onset of the objectives of the rule that has been in place for over 4 years, and summarized states: the establishment of a system of flexible controls (with exceptions) to prevent the transmission and amplification of the infectious agent of bovine spongiform encephalopathy (BSE) in the U.S. cattle herd through feed and thus minimize any potential risk to animal or human health.

When first proposed and subsequently finalized in a final rule format, it was a timely proactive measure to institute preventive public health controls in a country officially free of BSE. This BSE-free status is affirmed by extensive testing, surveillance, and epidemiological assessments performed by the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA), the agency responsible for the control of infectious diseases of animals in the country. Thus, based on any objective analysis, the current risk is lower than at any time since the initial reported outbreak of the disease in the United Kingdom in 1986. In essence, we are dealing with a foreign animal disease of which 99.999% of all cases are in Europe. Additionally, the U.S. has effective preventive controls, directives and regulations to preclude any likelihood of disease amplification.

Compliance with the rule is more than adequate, based on the agency's latest data and findings. This is substantiated by the rendering industry's third party certification inspection audit conducted by Cook & Thurber, Madison, Wisconsin.

In summary, the existing rule provides adequate public health protection based on all indicators of relative risk and in no apparent need for modifications of any kind.

2. Is the present rule at Sec. 589.2000 adequate to meet its intended objectives? If not, what are the inadequacies? Are there additional objectives that this rule should now address? If so, what are these new objectives?

As implied in inferences made in answering question 1, the rule more than adequately meets its planned objectives. There are no major inadequacies in the rule that would enhance risk (s) that could amplify the likely establishment or transmission of the infectious agent of BSE. Be advised, the rule was initiated in a country free of BSE as a proactive and preventive response to a disease thousands of miles away.

Additional objectives, over and above the existing rule including the concurrent policies that have been established in the U.S. over the past 15 years, and the industry's own internal controls would seem unreasonably demanding and arbitrary, and not a reflection of the present risk factors.

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 present FDA ban relative to use in ruminant feed needs no further broadening. The current regulation is working well and extensions of the rule would be prejudicial and not based on a reasoned examination or a reflection of the science. Actually, the inference and suggestion that much new information has emerged on BSE and vCJD must be put in perspective. The reality is that more point – counter point prevails than finite new findings that are universally accepted.

A reflection of the suggestion that new information has emerged could be considered acceptable to a degree but not applicable to the heart of the rule. For example, factors that could truly enhance the effectiveness of the rule e.g. the use of diagnostic tests for the identification of the infectious agent in feed are inadequate.

Any extension of the rule beyond ruminant feed would be devoid of scientific affirmation and would exceed all the current elements of risk assessment. It would also be a gross injustice to the U.S. rendering industry that has established on its own volition, prevention and control programs since 1989, and has worked with a focused agenda to assure compliance with the rule.

The rule basically applies only to prohibited material. The agency could enhance the "spirit" of the rule by regulating raw materials containing ruminant tissues disposed of by means other than rendering. They should be collected, transported, and processed by licensed rendering facilities (alluded to in other question) since the rendering industry has the infrastructure for traceability of raw materials and finished products. Raw materials that are derived from ruminants that are not subjected to rendering, makes the potential strong for cattle and other ruminants to be exposed to material prohibited by the rule, and compounding varying issues of compliance for the agency.

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 FDA ban provides specific record keeping and clean-out procedures to be followed by those facilities handling exempt and non-exempt materials. Feed manufacturers have successfully produced medicated and non-medicated feeds in the same facility without difficulty. Requiring the use of separate facilities for exempt and non-exempt materials would be prohibitively expensive, and the added cost would serve to make the feed rations financially unattractive with other competing ingredients. Additionally, this will reduce the efficiency of animal production and ultimately raise the cost of food to the consumer and an additional economic disadvantage to small independent mills that service more than one species.

The rendering industry has already instituted controls and measures in writing to prevent commingling as defined by the agency's compliance guidelines – sequencing, flushing, and the use of dedicated equipment. This is a subject that is addressed by the industry's internal audits and inspection, and the agency's own enforcement mechanism.

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

This is again a matter of compliance with the existing rule that needs no further elaboration or change. It is contrary to the rule, and not a practice of the rendering industry to transport prohibited and non-prohibited material in the same truck or container. The FDA ban provides vehicle clean-out procedures and paperwork documentation to control the procedures. A dedicated fleet for the purpose of transporting feed containing prohibited material would be cost prohibitive and would eliminate the use of animal proteins in multi-specie feed mills. Product identification of the hauled product and proper labeling serves to insure the integrity of transported products. Any modifications will increase the cost of transportation including the movement of non-prohibited proteins. This issue is currently not a problem.

6. In order to improve production practices and increase assurance of compliance with the rule, should FDA require licensing of renderers and other firms/facilities engaged in the production of animal feed containing mammalian protein?

The NARI coalition strongly supports and would participate in any effort to attain 100% compliance of the rendering industry. The industry will have no objections if a form of licensure would assist efforts to assure this compliance, provided that the process does not become a bureaucratic burden and creates undue requirements as a result. This could establish a systematic method for communication and formalize the present relationship with the industry that would benefit government – industry relations and aspects of mutual interest that could result in an overall improvement that would assist feed-food safety initiatives.

If FDA, however, were to enact such a requirement, the agency should be prepared to regulate and administer the regulation.

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)?

FDA's role as a public health agency should be constant vigilance and decisions should be made (especially in the modifications of an existing rule) on compelling scientific evidence. This should be dependent on a changing risk profile, preferably supported by peer review publications or on research findings that will support the proposed changes. NARI is unaware of any new information that will support any changes of the current exclusions in Sec. 589.2000 (a) (1).

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?

CVM made inferences and policy statements on this subject on June 14, 1998 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." The agency also obviously realizes that litter/manure may contain a small amount of poultry feed, and that commercial poultry producers take measures to limit and control spillage. (Poultry feed contains about 4%-5% protein meal, some or all of which may be non-prohibited). The amount of potential prohibited "carryover" material in litter/manure is therefore extremely small and the country is BSE-free, thus, precluding any potential for transmission or amplification of the infectious agent.

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

No. There is no reason to change the exclusion for cautionary labels on pet food sold at retail. Pet food products sold as distressed or salvage items should be labeled with the cautionary statement "Do not feed to cattle or other ruminants."

10. Should FDA extend its present record-keeping requirements beyond 1 year? If so, how many years?

It is doubtful that record-keeping requirements beyond a year are ever really indicated. In reality, the process could be counterproductive and cumbersome both to the agency and the regulated industry. In essence, it is difficult to conceive a real need to extend record keeping beyond a year. Nonetheless, NARI maintains an open mind on the likelihood of the need and recommends the agency consider the change only after a careful assessment of other options. In the era of computerization, it is hard to rationalize the proposal for any extension beyond the existing practice of one year.

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

No change or new adaptation is needed. The cautionary statement "Do not feed to cattle or other ruminants" circumvents this need. Actually, any deviation from existing feed labeling policies could create new problems by the development of new "compound" terms and confusion in interpretation and compliance. Livestock classes or species identification becomes cumbersome and devoid of real benefits. The marketplace will dictate the issue e.g. the current premium paid for porcine meat and bone meal exemplifies my position. This extension of the rule would only raise the cost of feed production without providing any additional safety factors.

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."

NARI has no problem with modifications that will enhance the objectives of the rule and amplify overall compliance including improved labeling. The suggestion, however, to include bison, elk, or deer has deceptive connotations because realistically the prohibited material is not used commercially in any of these referenced animals based on existing information. Nonetheless, NARI leaves the proposal to the discretion of the agency, and has no serious objections to the proposal as written.

13. What new information is available on potential efficient 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?

The ability of analytical methods to separate and detect extremely low level of "contaminants" has increased dramatically in recent years. However, it remains very difficult to assess accurately the presence of mammalian protein that is prohibited with the current available analytical methods that will produce results that are undisputable. All the issues of falsity with positives and negatives still prevail and they are limited to no opportunities for affirmation by the government based on existing technology. In essence, nothing exists that will create a comfort level, regulatory or legal.

NARI recommends that continuing research be encouraged by the agency to improve on the void that currently exists.

14. Regarding enforcement compliance with the rule, what further authorities, if any, would be desirable in order to enforce the rule adequately (civil monetary penalties? Others?

The current rule clearly demonstrates a system of checks and balances that ensures compliance by the industry and oversight responsibility/accountability of the regulating agency. The greatest challenge (to the agency) is maintaining a uniform system throughout the country in assessing compliance. This is especially problematic when 50 States are involved in one way or another in the determination of compliance.

There is no need to burden the regulated industries with the threat of civil penalties when they have demonstrated their willingness to cooperate and comply with the rule. There is no evidence that further authorities are needed to assess compliance.

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

The manufacture and production of safe feed ingredients is the responsibility of the rendering industry. It, therefore, behooves the industry, based on accountability, that there is an inherent obligation to establish systems to assure a safe finished product. Certification programs (public or private) could play a significant role in assisting the industry (and regulatory agencies) in achieving compliance. NARI affirms this suggestion based on experience with a voluntary fee-based third party certification inspection audit that achieved a 98% participation of producers of animal protein to validate compliance with the rule.

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

The import of feed ingredients and feed to the U.S. should be based on risk analyses and on a country's BSE incidence, as the predominant considerations. The U.S. could accomplish this by establishing a category classification as practiced in the European Union and Australia. The resulting import restrictions and policies would be based on this systematic classification category. It would be a structured and transparent process conducted by APHIS, USDA, and would have long-term benefits for disease control and a workable policy for an objective well-defined import policy.

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

The entire plan of instituted prevention in the U.S. is based on a sequential model that involves controls that are logical, commencing with a rule that prohibits the likelihood of the infectious agent of BSE to be transmitted through feed with the potential to infect cattle and subsequently then impact human health through the consumption of beef contaminated with the infectious agent (predominantly brain and spinal cord). The concurrent analogy is that the absence of BSE in a country would imply the likely absence of vCJD.

The mere fact that the "feed prohibition" to cattle was "formulated" over 4 years ago clearly indicates that the U.S. was proactive and took the needed measures to preclude any transmission to cattle and thus establish a preventive barrier to insure the protection of human health.

The rule was established in a country without any evidence of BSE affirmed by extensive surveillance, and a rigorous testing regimen that exceeds the protocol instituted by the Organization Internationale des Epizooties (OIE) in Paris as a recommended objective. As a result, NARI sees no need for additional measures based on the epidemiological record of the disease, the existing risk factors, and the controls already instituted.

SUMMARY

NARI takes this opportunity to respond to the questions that the agency considers important in the re-examination of various issues relating to the protein feed prohibition. A retrospective consideration of the subject demonstrates that after 4 plus years of the rule being in place, the rendering industry feels that the process is working well, and restates its commitment to work diligently with the agency to ensure compliance with the existing rule. As an industry, we see no need for any extensive modifications or changes, other than suggestions that were included that may enhance some future improvements, and heighten compliance.

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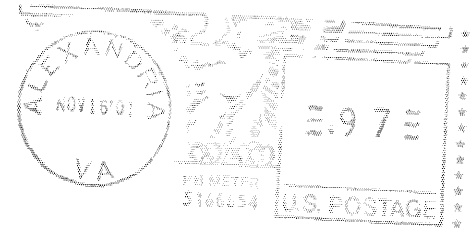

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