TAB 33

Comment on FDA rule (21 CFR589.2000) to prevent the establishment and amplification of BSE in the U.S. cattle herd.

Docket No. 01N-0423

Presented by Steven Roach at public hearing held in Kansas City, MO on October 30, 2001.

Food Animal Concerns Trust (FACT) is a non-profit organization that advocates better farming practices to improve the safety of meat, milk, and eggs. FACT has participated in developing the federal government's response to the threat of BSE to US agriculture, since the disease was first recognized. FACT was at the table when a federal strategy to keep U.S. cattle free from bovine spongiform encephalopathy (BSE) was fashioned several years ago, and FACT worked on the drafting of the FDA rule to prohibit certain types mammalian protein for ruminant feed which we are re-examining today. FACT's position on BSE is based on an awareness of the real risks of transmissible spongiform encephalopathies(TSE) to human and animal health combined with an acute sensitivity to the current scientific uncertainties on how this class of diseases is transmitted both within and between species.

FDA has requested public comments on several aspects of the existing rule to limit the spread of BSE through the regulation of animal feed. FACT commends the FDA for the work they have done so far in creating the original rule and in enforcing its provisions, but we feel that the time is ripe for a reevaluation of the regulation. Since 1997, we have seen the disease spread throughout Europe and it has now been found in Asia. The profile of the disease in Europe indicates how easily the disease can spread when controls on feeding are not stringently enforced[1]. The unexpected appearance of BSE in Japan suggests that other countries outside of Europe may have undetected cases and there is a real risk that feed stuff containing the disease will be imported into the U.S. It is important to note that we did not have restrictions on importing feed from Japan during the period when the disease was present but undetected. Because BSE is currently developing into a world wide problem spreading from its appearance in a single nation, the United Kingdom, FACT calls on the FDA to broaden the scope of the FDA ban and

to more rigorously enforce the current provisions. I will now discuss the questions on which FDA has requested comments.

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

FDA needs to respond quickly to operations that are out of compliance of the rule. In a recent report provided by the FDA's Center for Veterinary Medicine (CVM), over 500 businesses were found to be out of compliance[2]. Almost 400 of these firms that were out of compliance handle both ruminant and non-ruminant feed. Perhaps even more disturbing is the fact that 10 firms that handle both ruminant and non-ruminant feeds met none of the requirements of the law and had not been re-inspected since the end of 1998. We accept that the compliance inspection process is an arduous task, but here we have a clear case of law violation with no follow up in over two years. According to the rule, these businesses are clearly in violation of the act and are marketing illegally adulterated animal feed. If after a prompt follow up inspection the business is still not in compliance with the law, the FDA should use its authority to confiscate and condemn any illegally adulterated feed. This would obviously include any feed intended for sale as ruminant feed by the out of compliance entity.

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?

FACT believes that the current rule is too narrow in its scope and focus. The aim of the rule should be expanded to reduce the potential amplification of all TSEs and not focus so narrowly on BSE. The first way in which it should be modified is that there are too many exclusions on the types of protein that are regulated. The second area where the rule fails is that it does not sufficiently address the potential for the transmission across species barriers. These two failures will be addressed below in response to question

three. The third area where the rule fails is that the labeling requirements are not adequate to keep prohibited and non-prohibited materials from being commingled. This issue will be addressed under question 11 below.

3)Should the present FDA ban on the use of certain mammalian proteins in ruminant feeds be broadened? If so, what should the new parameters of use be? Should the rule be broadened beyond ruminant feed? Beyond mammalian protein?

TSEs have been found to affect humans, goats, sheep, mink, deer, elk, cattle, domestic and wild cats, zoo ruminants, and zoo primates[3]. Experimentally TSEs have been transmitted to mice and swine[4]. The transmissible agent for all TSEs is believed to be an altered form of a naturally occurring protein (prion) that builds up in central system tissue leading to neurological disorder and death[5]. In addition to being found in nervous system tissue, the transmissible agent is also found in lymphatic tissues, intestines, and blood[6]. For each of the known TSEs, as FACT understands it, there is still uncertainty about how the infectious agent is transmitted and about how the disease develops during incubation. When interspecies transmission is included, the picture becomes even murkier. In the case of BSE, there is evidence of transfer between cattle and many other species including felines, zoo, ruminants, and humans. While it is clear that there exist barriers to the transmission of TSEs between species, the nature of these barriers is little understood.

Therefore, FACT urges the FDA to limit the exclusion on mammalian proteins allowed for feeding to ruminants to milk and milk products and to products made exclusively of porcine or equine protein. The current exclusion on blood products is unacceptable given the clear evidence of infectivity in blood[7]. Similarly there is no justifiable reason to exclude food offered for human consumption such as plate waste. This is particularly important given the potential for unspecified material of foreign origin in plate waste such as was implicated in the outbreak of foot and mouth disease in the United Kingdom.

Because of continuing evidence regarding the potential to transfer TSEs between species, FACT recommends that the FDA review whether or not restrictions should be placed on the use of any animals with neurologic disorders as feed for any livestock including poultry, equines, and swine. The use of materials from the bovine central nervous system should be banned along with the use of bovine materials from any countries with a high risk for BSE for any animal feeding purposes.

4. Should the 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?

Dedicated facilities are the only way to insure that commingling does not occur given the inability of the regulatory agencies to maintain a daily presence in the facilities. This is particularly important given the recent history in Europe where commingling is implicated in many of the recent cases of BSE. If dedicated facilities are not required, a mechanism must be put in place that prohibits repeat violators of the rule from marketing feed intended for ruminants. One approach to this would be requiring licenses for all producers of feed containing mammalian protein. This will be addressed further in the response to question 6.

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

It is FACT's position that dedicated transportation is the only way to insure that commingling does not occur during transportation.

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?

Where FDA does not currently license feed preparation, licensing other establishments would be an excellent tool for increasing compliance with the rule. If it is not feasible to license all facilities, a subset of facilities could be licensed. Facilities that produce feed for ruminants could be licensed or facilities that handle both ruminant and non-ruminant feeds could be licensed. Licensing would need to be combined with enforcement to make it an effective tool. Licensing combined with monitoring using analytical methods that distinguish between prohibited and non-prohibited materials could provide a much higher level of compliance than our current system with its less than annual checks.

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)?

As stated in our reply to question 3, FACT believes that exclusions should only be allowed for milk products and products whose only mammalian proteins consists entirely of porcine and equine protein. FACT also believes that the exclusion for swine and equine proteins should not apply to protein from animals with neurologic disorders.

8. Should FDA add to the list of prohibited material in ruminant feed poultry litter and other recycled poultry waste products?

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

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

Records should be kept for a minimum of 5 years. FACT pushed for this provision when the rule was first considered and FACT still believes it is an important provision. Because the incubation period for BSE is 4 to 5 years[8], FACT urges FDA to require that records be kept for at minimum 5 years to provide the information necessary to trace the source of infection in the case of an outbreak.

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"?

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."?

13.What new information is available on potential efficient, accurate analytical methods that may be used tin detecting mammalian proteins, especially the prohibited mammalian proteins, in feed and what should the sampling parameters of such a program be?

FACT does not have information on new analytical methods, but encourages the FDA to seek out such methods to use as part of its compliance monitoring efforts.

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?, other?)

FDA should use its existing authority to condemn adulterated product as defined in the rule in the case of consistent non-compliance. FDA should seek to extend its authority to investigate potential violations that occur where feed is mixed on farm.

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

Certification programs should be used to educate feed producers and handlers on the rule, and to help them develop better internal control systems. FDA should not view certification programs as a justification for lessening its own compliance monitoring program.

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

FACT urges the FDA to follow Office International Des Epizooties standards and conduct risk assessments on individual countries. Given the risk of importing BSE infected feed into the U.S., imported feed containing animal proteins should not be used in feeding ruminants unless the country of origin has demonstrated effective rules for the segregation and labeling of feed that are equivalent to U.S. rules.

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

FACT believes that much more work needs to be carried out on basic research on BSE and other TSEs. One area that is absolutely essential is the development of a diagnostic test that can be used on live animals. More research also needs to be done on the nature of the species barriers between the different TSEs.

In summary, FACT urges FDA to continue its current efforts to control the potential spread and amplification of BSE. In addition, FACT calls on FDA to strengthen its efforts by broadening the range of prohibited products to include all ruminant proteins and by taking further precautions with the most at risk materials such as proteins from animals with neurological disorders. In the area of monitoring of compliance, FDA needs to step up re-inspection of non-complying firms and if necessary to use its authority to condemn feed that is adulterated by definition of the provision.

Notes:

1) Latest develoments on BSE, Statement by David Byrne, European Commisioner for Health and Consumer Protection. Agriculture Council, Luxemborg, 23 October 2001. Available on line at http://europa.eu.int/comm/dgs/health_consumer/library/speeches/speech127_en.pdf

2) CVM and Ruminant Feed (BSE) Inspections. Data current through October 9, 2001. Available on line at http://www.fda.gov/cvm/efoi/InpectionListDescriptionforHP.htm

3) Technical report: Transmissable Spongiform Encephalopathies: A Review for Pediatricians(T109906), Whitley et al. Pediatrics 106(5):1160-1165. Available on line at:www.aap.org/policy/t109906.html

4) Intra-Species Recycling – Opinion on:the risk born by recycling animal by-products as feed with regard to propagating TSE in non-ruminant farmed animals. Adopted on 17 September , 1999. European Commission, Health and Consumer Protection - Scientific Steering Committee. Available on line at:europa.eu.int/comm/food/fs.sc.ssc.out60_en.html.

5) Creutzfield-Jakob Disease and Related Transmissible Spongiform Encephalopathies. Johnson and Gibbs. New England Journal of Medicine December 31, 1998:1994-2004.

6) Detection of variant Creutzfield-Jacob Disease infectivity in extraneural tissues. Bruce et al. Lancet 358:208-209.

7) Transmission of BSE by blood transfusion in sheep. Houston et al. Lancet 356:999-1000

8) Bovine Spongiform Ecephalopathy Disease Card. Office International Des Epizooties. Available on line at:www.oie.int/eng/maladies/fiches/a_B115.htm