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Comments from Food Animal Concerns Trust (FACT) in response to the
Food and Drug Administration's (FDA)
Proposed Rule Substances Prohibited From Use in Animal Food or Feed

Comments submitted by
Richard Wood, Executive Director and Steven Roach, Food Safety Program Manager

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Food Animal Concerns Trust (FACT) is a non-profit organization that advocates better farming practices to improve the safety of meat, milk, and eggs. Since Bovine Spongiform Ecephalopathy (BSE) was first recognized in the mid 1980s, FACT has worked diligently with Federal regulatory agencies to develop an appropriate response to the threat to human and animal health presented by this fatal degenerative disease. This is the fourth time since October 2001 that FACT has submitted written comments to the FDA addressing the adequacy of the ruminant feed ban. Since last submitting comments in August 2004, there has been a confirmed case of BSE in a cow born in the U.S. FACT hopes that FDA will act without further delay to move forward with a final rule.

General Comments

FACT supports the FDA's decision to remove the highest risk materials (SRMs) from all animal feeds. Focusing on those materials at highest risk for infectivity is consistent with current scientific evidence and international accepted standards. While FACT believes

that a SRM ban is an appropriate part of a program to control the transmission of BSE through feed, we disagree with FDA's choice to allow 10% of potentially infectivity into the feed stream. Accepting the FDA's figure of 7800 ID50s per infected cow, the FDA proposal would allow 780 ID50s for each animal not identified as BSE positive at slaughter or before rendering.

FACT also disagrees with the FDA's proposal to allow poultry litter, plate waste, and blood products in ruminant feeds and failure to take further steps to prevent cross contamination between ruminant and non-ruminant feeds. The failure to ban the feeding of poultry litter is particularly egregious given the FDA's decision to allow 10% of infectivity to be allowed in feed. FACT calls on FDA to implement the steps it announced in January 26, 2004 in addition to implementing the SRM ban. As FACT noted in our previous comments, the steps announced in January 2004 were consistent with those recommended by international review team (IRT) convened by the Secretary of Agriculture that same month. FDA has ignored scientific evidence and international norms in this proposed rule. The inadequacy of the rule could lead to further cases of BSE, which would once again lead to the closing of international markets, and could eventually lead to human BSE cases.

Detailed Comments

FACT recommends that FDA use the same definition of SRM as used for human food.

This would include a ban on the use of downed animals in animal feeds. There is no scientific justification for allowing 10% of infectivity into the feed stream. This is

particularly important given the recent finding of a lower minimum infective dose for BSE noted in the proposed rule as reported by the European Commission's Scientific Steering Committee (SSC) in June 2003. Allowing 10% of potentially infective material in the feed stream, will also create difficulties in verifying the efficacy of controls designed to remove the other 90% of infectivity. Detecting CNS tissue in rendered materials is already difficult, allowing a portion of ruminant CNS tissue in feeds would eliminate incentives to develop more sensitive tests.

FACT recommends that FDA make clear that the ban on feeding ruminant protein to cattle includes poultry litter. Poultry litter is known to contain spilled feed containing meat and bone meal, so feeding this material is inconsistent with a ban on feeding ruminant MBM to ruminants. As noted in comments to the FDA by the State of California Department of Food and Agriculture (CDFA, 2003), meat and bone meal can be detected by microscopic examination of dried poultry litter. In the state of California alone, up to 80,000 tons of poultry litter are fed each year. Applying the estimate of the quantities of spilled feed from the North American Rendering Industry (NARI, 2004), referenced in the proposed rule, to California finds that 3680 tons of MBM are fed annually to cattle in California alone. $80,000 \times 0.23 \times 2 = 3680$. We included a factor of 2 because the NARI includes only the protein part of MBM.

Allowing any ruminant derived MBM into ruminant diets violates the conditions of the OIE World Organization for Animal Health Terrestrial Animal Health Code conditions for either negligible or controlled risk for BSE and could be used as the basis for closing

markets to US cattle and beef. If any one major importer decided to ban US beef because of this gap in the US ban on feeding MBM to ruminants, the lost revenues would easily outweigh the economic benefit to cattle producers or poultry growers from feeding litter. Under OIE guidelines, a country will not be considered a negligible or controlled risk until eight years after the feeding of MBM has stopped. The sooner this practice is stopped the better to insure that US cattle producers are not kept out of markets for years to come.

The preliminary risk assessment by the North American Rendering Industry (NARI, 2004) makes several flawed assumptions that lead to a great underestimation of the risk. The NARI estimate assumes that the poultry gut is 100% efficient at destroying all protein digested including converted prions that are known to be protease resistant, and also assumes perfect mixing during rendering and at clean up of poultry houses down to the milligram level at which infectivity has been shown. The FDA partially corrects this by looking at the possibility that there was limited mixing at clean out, a more realistic assumption than the complete mixing assumed in the NARI estimate.

If the FDA modified NARI risk estimation is redone, even ignoring the resistance of converted prions to degradation, and instead applies the normal digestibility of proteins in MBM, a very different assessment of risk is found. Digestibility of the crude protein content of MBM for poultry ranges from 75 to 80 percent (Leeson and Summers, 2001). Taking the higher number of 80% digestibility, leaves 20% indigestible protein in MBM when fed to poultry. This would result in 21% of the protein of fed MBM making it to

the litter - one percent spilled and 20% undigested. If FDA's calculation that a cow would need to eat 3.4 tons of poultry litter to ingest 1 ID50 is modified to include this much greater percent of animal protein making it to the litter, 21% versus 1%, the result is that a cow would need to eat only 324 pounds of litter to consume 1 ID50. As noted in the NARI estimate a cow might eat 10 pounds of litter a day, so 1 ID50 could be consumed in little over a month not the 17 years estimated by NARI. During a single gestation, a cow could easily consume 8 ID50s.

The above calculation does not take into account the scientific evidence that converted prion proteins are resistant to proteolytic enzymes and to low pH levels (Taylor, 2000). Experience with mice has shown that infectivity can be detected after passage through the gut and experts recommend that manure from animals that have been fed potentially infected MBM not be used as animal feed. (WHO/FAO/OIE, 2001). The available scientific evidence indicates that BSE infectivity is expected to pass through the poultry gut and be available in litter for consumption. Because of this, the estimation of BSE risk in poultry calculated above may actually be low. FACT assumed that 80% of infectivity would be eliminated by passage through the poultry gut.

The NARI estimate also assumes that perfect mixing occurs during rendering and within the poultry house during clean out. The FDA made a correction for incomplete mixing during clean out in the poultry house, but accepts NARI's assertion that perfect mixing occurs during rendering. The BSE Inquiry (BIR, 2000) carried out in the United Kingdom considered the "packet" theory of MBM distribution as an explanation for the

low level of within-herd incidence of BSE. At the time the report was completed in 2000, the committee was unable to come to a conclusion on the “packet” theory because the necessary packet size seemed to be too large given the particle size of rendered product and the assumption of a fairly large infectious dose at that time. Given the more recent data showing infectivity at the 10 milligram level, the packet theory seems much more likely to be correct. In testimony to the BSE inquiry, S.L. Woodgate testified that a 1 gram packet making it from raw material to consumer was possible (Woodgate, 2000). Packets of milligram size are even more likely.

This problem was addressed by the SSC (2003, page 211) in a discussion of what is the appropriate batch size for risk assessments. The report notes that for some products such as melted fats, an assumption of complete mixing is appropriate but for “other processes the raw materials may remain in the production process as discrete amounts or are only partly mixed and the possible presence of residual infectivity (if any) may be limited to a given fraction of the end-batch. In the latter case, the dilution effect is lower and limited to the size of the discrete amounts of raw material that entered the production chain.” In making its risk assessment, NARI has assumed that rendered product behave as a melted fat with perfect mixing. A more conservative assumption would be to assume that beyond the 1 log infectivity decrease from temperature, rendering would lead to the same discrete number of ID50s independent of how much material is added to the original BSE source. These ID50s would be concentrated in discrete packets in poultry feed, so that a cow could eat a single dropped feed pellet and ingest an ID50 not the pounds of feed assumed above.

FACT recommends that FDA require dedicated facilities and equipment. Given the decision expressed in the proposed rule to allow 10% of infectivity into the animal feed system, FACT believes it would be wrong to allow the limited number of facilities still handling ruminant and non-ruminant feeds to continue to use shared equipment for both types of feed. Even if a more thorough SRM ban were to be put in place, errors in identifying at risk cattle and in removing SRMs would still occur making the risk from dual purpose facilities too high. Most feed handlers have already taken the necessary steps to protect their customers. FDA should level the playing field and require all facilities to either invest in dedicated equipment, or decide to handle one type of feed. The recent information on the lower infectious dose makes this requirement imperative.

FACT recommends that FDA move forward with the decision to ban plate waste and blood products as announced in January 2004. Removing SRMs does not change in anyway the risk from these two routes of possible infection transmission. The scientific basis for the original announcement still holds. In respect to plate waste, the FDA acknowledged in the proposed rule that feeding plate waste to cattle is rare. Given the small number of businesses that would be affected, the FDA should stand behind the scientific evidence that ruminant proteins should not be fed to animals. Feeding plate waste also puts US producers at risk for market loss if an importing country decides that this breach of the MBM ban violates the OIE conditions for negligible or controlled BSE risk. While BSE infectivity to cattle through blood has not been shown, infectivity to transmissible spongiform encephalopathies in blood have been shown in a wide range of

other species. It is unwise for FDA to assume that cattle are the unique exception to transmission of TSEs through blood.

Conclusion

FACT hopes that FDA will carefully consider these comments and move forward with a final rule. FACT recommends that FDA require that all potentially infected materials be removed from animal feed not just the 90% in the proposed rule. FACT also strongly recommends that FDA abandon the decision to allow poultry litter to be fed to cattle as it is contaminated both with spilled feed and with undigested animal protein. The other loopholes that allow the feeding of ruminant protein to ruminants should also be closed.

The current proposed rule leaves too many pathways open for the transmission of infection. FACT recommends that these pathways be closed to protect cattle, cattle producers, and most importantly the American general public. Thank you for this opportunity to provide these comments.

References

BIR, 2000. The BSE Inquiry Report, vol. 2, Science, A committee report to MAFF, UK.

BSE Inquiry <http://www.bseinquiry.gov.uk>

CDFA, 2003. Comments from the California Department of Food and Agriculture to FDA Docket No. 02N-0273, January 22, 2003.

Leeson and Summers, 2001. Nutrition of the Chicken. University Books, Guelph.

NARI, 2004 North American Rendering Industry submission to docket number 02N-0273, comment 30, February 3, 2004.

SSC, 2003. Overview of the BSE risk assessments of the European's Commission Scientific Steering Committee (SSC) and its TSE/BSE ad hoc group, Adopted between September 1997 and April 2003, June 5, 2003.
http://europa.eu.int/comm/food/fs/sc/ssc/out364_en.pdf

Taylor, 2000. Inactivation of Transmissible Degenerative Encephalopathy Agent: A Review. The Veterinary Journal 159:10-17.

WHO/FAO/OIE, 2001. Joint WHO/FAO/OIE Technical Consultation on BSE: public health, animal health and trade. OIE Headquarters, Paris, 11-14 June 2001.
http://www.who.int/csr/resources/publications/bse/WHO_CDS_CSR_APH_2001_8_EN/en/

Woodgate, 2000. The BSE Inquiry, Statement No. 39C.
<http://www.bseinquiry.gov.uk/files/ws/s039c.pdf>