

December 19, 2005

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

Re: Docket No: 2002N-0273 (formerly Docket No. 02N-0273)

Substances Prohibited From Use in Animal Food and Feed

Dear Sir or Madame:

The McDonald's Corporation buys more beef than any other restaurant in the United States. It is essential for our customers and our company that the beef has the highest level of safety. Concerning BSE, the most effective way to insure this is to create a system that processes cattle that are not exposed to the disease. As a company we take numerous precautions via our strict specifications to help and assure this, however we feel that the force of federal regulation is important to ensure that the risk of exposure in the entire production system is reduced to as close to zero as possible. The exemptions in the current ban as well as in the newly proposed rule make this difficult if not impossible, as there are still legal avenues for ruminants to consume potentially contaminated ruminant protein. In addition, the USDA still has not implemented a system of identification and traceability. It is our opinion that the government can take further action to reduce this risk and appreciate the opportunity to submit comments to this very important proposed rule.

After the identification of bovine spongiform encephalopathy (BSE) in indigenous North American cattle, the U.S. Department of Agriculture (USDA) responded rapidly to implement measures to protect public health in regard to food. Our company recognizes and supports the importance of the current feed ban which went into effect in August 1997. However, given what is known about the epidemiology and characteristically long incubation period of BSE, we urge the FDA to act without further delay and implement additional measures which will reduce the risk of BSE recycling in the US cattle herd. We caution against using the 18 month enhanced surveillance as a justification to relax or impede further actions. While this surveillance indicates an epidemic is not underway, it does not clear the US cattle herd from infection. The positive cases indicate probable exposure prior to the 1997 feed ban, a time when BSE appears to have been circulating in animal feed. BSE cases are most likely clustered in time and location, so while enhanced surveillance provides an 18 month snapshot, it does not negate the fact that US and Canadian cattle were exposed to BSE and that the current feed controls contain "leaks".

We feel that for the FDA to provide a more comprehensive and protective feed ban, specified risk materials (SRMs) and deadstock must be removed from all animal feed and that legal exemptions which allow ruminant protein to be fed back to ruminants (with the exception of milk) should be discontinued.

SRMs, as defined by the USDA, are tissues which, in a BSE infected animal, are known to either harbor BSE infectivity or to be closely associated with infectivity. If SRMs are not removed, they may introduce BSE infectivity and continue to provide a source of animal feed

contamination. Rendering will reduce infectivity but it will not totally eliminate it. This is significant, as research in the United Kingdom has shown that a calf may be infected with BSE by the ingestion of as little as .001 gram of untreated brain.

The current proposed rule falls short of this and would still leave a potential source of infectivity in the system. In fact by the FDA's own statement the exempted tissues which are known to have infectivity (such as distal ileum, DRGs, etc) would cumulatively amount to approximately 10% of the infectivity in an infected animal. Leaving approximately 10% of the infectious tissues in the system is not good enough. The proposed rule still allows the possibility for cattle to be exposed to BSE through:

1. Feeding of materials currently subject to legal exemptions from the ban (*e.g.*, poultry litter, plate waste)
2. Cross feeding (the feeding of non-ruminant rations to ruminants) on farms; and
3. Cross contamination of ruminant and non-ruminant feed

We are most concerned that the FDA has chosen to include a provision that would allow tissues from deadstock into the feed chain. We do not support the provision to allow the removal of brain and spinal cord from down and deadstock over 30 months of age for several reasons. These are the animals with the highest level of infectivity in tissues which include more than brain and spinal cord. Firstly, there are two issues regarding the complex logistics of this option. We do not feel that it is possible to have adequate removal especially during the warmer months. In addition, we do not feel that there are adequate means to enforce complete removal. Unlike slaughterhouses, there are no government inspectors at rendering plants or deadstock collection points.

Most importantly, there is emerging information that at end stage disease (a natural BSE case); infectivity may also be included in additional tissues such as peripheral nerves (Buschmann and Groschup, 2005 – see attached). This published work supports publicly reported studies in Japan where by western blot testing, prions have been found in the peripheral nerves of a naturally infected 94-month-old cow. If this is the case, the amount of infectivity left in the system from an infected bovine would surpass 10% and the full extent is still unknown.

McDonald's has convened its own International Scientific Advisory Committee (ISAC) as well as co-sponsored a symposium of TSE scientists on the issue of tissue distribution. The consensus of both groups was that the pathogenesis of BSE might not be entirely different from TSEs in other species at the point where the animal is showing signs of the disease. These scientists feel that the studies as reported above have merit. The current studies not only re-enforce the risk of down and deadstock but also appear to provide additional information that these animals may be a potential source of greater levels of infectivity into the feed system. Hence, we suggest that the FDA consult with TSE scientists as well.

Leaving the tissues from the highest risk category of cattle in the animal feed chain will effectively nullify the intent of this regulation. This point is illustrated by the 2001 Harvard risk assessment model that demonstrated that eliminating dead and downer, 4D cattle, from the feed stream was a disproportionately effective means of reducing the risk of re-infection.

“The disposition of cattle that die on the farm would also have a substantial influence on the spread of BSE if the disease were introduced.” The base case scenario showed that the mean total number of ID50s (i.e., dosage sufficient to infect 50 percent of exposed cattle) from healthy animals at slaughter presented to the food/feed system was 1500. The mean total number of

ID50s from adult cattle deadstock presented to the feed system was 37,000. This illustrates the risk of “4D cattle” (i.e., deadstock).

From the Harvard Risk Assessment, 2001, Appendix 3A Base Case and Harvard Risk Assessment, 2001 Executive Summary

McDonald’s also urges agencies of the US government to work with academia and industry on research in the following areas:

- Methods to inactivate TSEs agents which then may allow a product to be used and even fed to animals without risk
- Alternative uses for animal byproducts which would maintain some value

In July 2004, McDonald’s in cooperation with others sponsored a meeting at Penn State. The purpose of the meeting was to review work conducted by Dr. Bruce Miller looking at the feasibility of using carcasses and animal byproducts as renewable alternatives to fossil fuels in large energy generating boilers. A number of government representatives were also invited to this meeting. We are aware that Dr. Miller continues this work which shows great promise. We suggest that the FDA explore the possibility of this alternative use that may also have a positive impact on the environment.

The McDonald’s Corporation will continue to work with the FDA and other government agencies to implement a strong BSE risk control program. We would like to reiterate our opinion that for the FDA to provide a more comprehensive and protective feed ban, specified risk materials (SRMs) and deadstock must be removed from all animal feed and that legal exemptions which allow ruminant protein to be fed back to ruminants (with the exception of milk) should be discontinued. Thank you for the opportunity to submit these comments to the public record.

Respectfully,

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