



WENDY'S INTERNATIONAL, INC.

THOMAS J. MUELLER

President and Chief Operating Officer

North America

RECEIVED
FSIS DOCKET ROOM

04 MAY -7 AM 11:40

619

May 5, 2004

Ann M. Veneman
Secretary
U.S. Department of Agriculture
1400 Independence Avenue, S.W.
Washington, D.C. 20250

Reference Docket Numbers: 03-025IF; 03-038IF; 01-033IF

Dear Secretary Veneman:

Wendy's International, Inc. is one of the world's largest restaurant operating and franchising companies. We were founded in 1969 by Dave Thomas and are the third largest quick-service hamburger restaurant chain in the world, with more than 6,500 restaurants in the United States, Canada and international markets. We appreciate your consideration of the following comments on the federal government's response to Bovine Spongiform Encephalopathy (BSE). Wendy's International, Inc. has no greater priority than food safety and appreciates that the Department shares our goal of advancing and protecting the safety of the American food supply. We welcome any opportunity to work with you toward this goal.

Cattle Identification

We support a mandatory cattle ID program to enable full traceback of cattle. We understand the Animal and Plant Health Inspection Service (APHIS) currently has the authority to implement such a program, and we commend the Department for beginning this effort.

The experience with both cases of BSE in North America illustrates the need for an identification and traceability system in the United States. In addition, if the United States were to experience an outbreak of another disease such as Foot and Mouth Disease (FMD), identification would also be essential to track movements of exposed animals. The FMD outbreak experienced by the United Kingdom in 2001 illustrates the absolute importance of identification.

A national system of full traceback to farm of birth, complete with all movements recorded is needed. We are aware that it may take over 5 years to fully implement a system that tracks animals from birth, however we urge the Department to start the issuance of premise IDs to begin building the framework of the identification system.

Ban on Nonambulatory Cattle (Docket Number 03-025IF)

Wendy's supports the USDA's actions prohibiting the slaughter of nonambulatory cattle for human consumption. This is consistent with our own policy which has been in place since 2001.

Prohibiting nonambulatory cattle from being incorporated into human food eliminates a BSE high risk category of animal from the food supply. The action reduces the potential of human exposure to the BSE agent through cross contaminated meat products.

Data collected in Europe clearly establishes fallen stock and emergency slaughter cattle as one of the highest risk populations in regards to BSE. These cattle accounted for over half of the detected BSE cases in both the EU and Switzerland in 2003. In 2003, this population accounted for 52.4% of the BSE cases in Switzerland and 55.4% of the cases in the EU (according to the European Commission's website "Europa", Swiss Department of Economic Affairs, Federal Veterinary Office).

Determining the underlying cause of an animal's illness once it is nonambulatory is often extremely difficult if not impossible. The total inability to rise often prohibits the display of other clinical signs such as incoordination, gait abnormalities, weakness, tremor, etc.

BSE can be one of the diseases that causes a cow to become incoordinated which then predisposes the cow to fall, increasing the chances of an injury. We urge that the Department not change the definition of nonambulatory disabled cattle to allow for any exceptions. Wendy's strongly supports the definition of nonambulatory disabled cattle to include any animal which cannot walk to the stun box on its own accord regardless of reason.

Increased Surveillance/Testing

We applaud the Agency and support the expanded testing program for surveillance as recently announced by USDA. We urge USDA, APHIS and FSIS to commit all the necessary resources and accomplish the goal of collecting and testing over 260,000 samples.

Establishing a baseline level of disease in the United States is essential to guide decisions in regards to further risk reduction measures which may be needed. It will also allow a method to track the effectiveness of current control measures.

Ban of Air Injection Stunning (Docket Number 01-033IF)

Wendy's supports the USDA's rule banning the practice of air-injection stunning or other procedures which would dislocate gross portions of the brain into the circulatory system. Given that the brain is considered a high risk tissue in regards to BSE, we feel that this action is consistent with the other protections. In fact, for years our suppliers have not used this equipment.

Ban of Advanced Meat Recovery (ARM) Practices (Docket Number 03-038IF)

Wendy's supports the proposed rule regarding Specified Risk Material (SRM) removal and restrictions placed upon AMR product. Wendy's feels that these regulations are based on sound science and are necessary to provide additional protection to the US food supply.

Wendy's fully supports the prohibition on vertebral columns and skulls from cattle over 30 months of age from being used in AMR product. In addition, we support the rule prohibiting spinal cord and DRG from being in AMR product for cattle less than 30 months of age. We also note that AMR has never been allowed in our product specifications.

There is ample justification to prevent the use of vertebral column and skull from cattle over 30 months of age in AMR systems. Although the spinal cord should be removed as dictated by government, there can be infectivity presented to AMR from the dorsal root ganglia and potentially from the dura (covering of the spinal cord). It is difficult to completely separate infectivity from the dura due to its close association with the cord. Also, if the carcass is missplit or if the removal is done poorly, spinal cord may enter AMR product.

In addition, all Harvard risk assessment scenarios found that AMR delivered more infectious doses to people than brain and spinal cord combined.

Specified Risk Material (Docket Number 03-025IF)

Wendy's supports the proposed rules promulgated by the USDA in regards to SRM removal and restrictions placed upon AMR product. Wendy's feels that these are based on sound science and are necessary to provide additional protection to the US food supply.

Wendy's urges USDA to diligently insure that SRMs are being removed using methods which eliminate cross contamination of product intended for human consumption.

Regarding the science, the bovine tissues considered as specified risk materials (SRMs) include those tissues where infectivity has been detected (i.e. these tissues are able to transmit BSE), as well as structures such as the skull and vertebral column where complete removal of infected tissues would not be possible.

Wendy's suggests that the prohibition on small intestines be expanded to include intestines from duodenum to rectum. Although, studies conducted in the United Kingdom, found detectable infectivity in the distal ileum (small intestine) of calves at 6 months post feeding positive immunostaining was found throughout the entire length of the intestine.

We understand that infectivity studies are still ongoing and the list of tissues is subject to change pending these findings. Also, as the USDA conducts its surveillance, if cases of BSE are found to be in additional animals, we urge the Department to make adjustments to these rules as needed to protect the entire food supply.

Food And Drug Administration - Ruminant Feed Bans

Wendy's appreciates the USDA action to protect the food supply and the American public. However, it is essential that the FDA expand its rules as recommended by the International Advisory Committee and prevent risks associated with cross contamination of feed for ruminants and the cross feeding of ruminants with potentially contaminated feed. Keeping the disease from recycling in cattle also guarantees a safer food supply.

Thank you, for your consideration of these comments.

Sincerely,

Thomas J. Mueller

A handwritten signature in black ink that reads "Tom Mueller". The signature is written in a cursive style with a large, looped initial "T".

President and COO

Wendy's North America

CC: Lester M. Crawford, DVM, PhD
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Docket Clerk
U.S. Department of Agriculture
Food Safety Inspection Service
300 12th Street, SW.
Room 102 Cotton Annex
Washington, D.C. 20250