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May 7, 2004

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

**RE: Docket Number 01-0331F
Docket Number 03-0251F
Docket Number 03-0381F**

Dear Sir or Madame:

McDonald's Corporation is pleased to submit the following comment in response to:

Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle; Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems; Prohibition of the Use of Certain Stunning Devices Used To Immobilize Cattle During Slaughter; Bovine Spongiform Encephalopathy (BSE) Surveillance Program

Docket Number 01-0331F: Prohibition of the Use of Certain Stunning Devices Used to Immobilize Cattle During Slaughter

McDonalds fully supports the prohibition of all devices which may cause the release of brain macro-emboli into the circulatory system of stunned cattle. Research has shown that certain devices which had been in use in the United States were more prone to this occurrence. In fact, when McDonalds was made aware of these findings we took proactive steps to prohibit this practice in any slaughterplant where our product was obtained. Our specifications were changed within 72 hours. We are also aware that most if not all of the industry followed suit.

Docket Number 03-0251F: Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Nonambulatory Disabled Cattle

Nonambulatory Disabled Cattle

McDonalds fully supports the Department's decision to remove nonambulatory disabled cattle from the supply of food for human consumption and agree with the definition as written in the Interim Final Rule. We urge the USDA to not alter this definition and to continue to prohibit for human food any animal which cannot walk to the stun box.

There are numerous causes for the nonambulatory condition in cattle. Some of these are clearly neurological in nature and others are not. Conditions such as injuries, certain mineral or vitamin deficiencies, tumors, other neurologic diseases, toxicities (chemical, plant, etc), and systemic disease either viral or bacteriologic in nature, etc. may dispose an animal to have difficulty in rising or go down permanently. In many instances, determining the reason that an animal is down is often extremely difficult if not impossible without a full diagnostic workup with numerous tests.

In addition, certain diseases (metabolic, viral, etc) may predispose an animal to become weak or incoordinated, resulting in an injury such as a broken leg. BSE is one such disease. In these cases, the injury is a result not a cause. Clinical observation often results in only diagnosing the obvious injury. In fact, this was the situation with the BSE case found in the State of Washington. The injury was apparent, but because the cow had no or at least did not display observable signs of neurologic disease she was passed for human consumption. The case on Canada in May was also not pulled out of the surveillance system as a BSE suspect. It presented and was condemned as a downer with pneumonia.

It has been a policy for many years that nonambulatory animals were not allowed to be processed for McDonalds beef.

Specified Risk Materials (SRMs)

McDonalds commends and fully supports the removal of specified risk material from the human food chain. This is in concurrence with the recommendations of the International Committee appointed by the Secretary, the World Health Organization and our own International Scientific Advisory Committee.

We feel that at this time none of the tissues should be deleted from the list as this prohibition is essential in protecting human health. In fact the Harvard Study concluded, "Implementation of a UK-style ban on specified risk material (e.g., spinal cords, brains, vertebral columns) from both human food and animal feed reduces the predicted number of BSE cases in cattle by 80% and the potential human exposure by 95%."

SRMs as defined by the interim final rule are those tissues which have been shown to be infectious when taken from cattle with BSE or those tissues having close association with the infected material.

At this time, McDonalds suggests that there be two additions to the list of SRMs. The first is dura (the covering around the brain and spinal cord). While skull and vertebral column are included as SRMs, dura is not. If dura is not removed and destroyed prior to processing on the fabrication floor, it may come loose and be incorporated into ground product. Bovine dura was never tested for infectivity. It was assumed that due to direct contact with spinal cord, it may serve as a vehicle to transmit disease. In addition, human dura has been the source of human to human transmission of Creutzfeldt-Jakob Disease (CJD). (personal communication – Dr. Danny Matthews, UK, VLA. Our ISAC committee recommended that McDonalds add the removal of dura as a specification in the production of our product.

We also suggest that the entire intestine be prohibited for human consumption as positive immunostaining for prion protein has been found throughout the intestine.

McDonalds urges USDA, FSIS to assure that each slaughterplant which processes cattle have systems in place which prevent cross contamination between edible tissue and SRMs. This should include separate equipment, such as knives, blades, etc where appropriate and utilize effective (for TSE agents) disinfection procedures for equipment used to handle SRMs.

McDonalds urges the USDA to make the appropriate adjustments in the SRM ban if new scientific findings and/or the results of the increased surveillance warrant a change.

Docket Number 03-038IF: Meat Produced by Advanced Meat/Bone Separation Machinery and Meat Recovery (AMR) Systems and Docket Number 03-025IF: Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Nonambulatory Disabled Cattle

McDonalds has never allowed the use of AMR or mechanically separated product in beef for our restaurants.

McDonalds fully supports all of the conditions and prohibitions placed on the production of product from AMR systems. McDonald's has never permitted use of product derived from AMR.

Given that infectivity has been found in brain, spinal cord, trigeminal and dorsal root ganglia, there is scientific justification to require that all precautions be taken to assure that these tissues are not included in any product for human consumption, including AMR. In this regard we also urge that dura be considered a SRM and be exclude from all human food including AMR product. Bovine dura was never tested for infectivity. It was assumed to be a possible risk due to the direct contact with spinal cord. In addition, human dura has been the source of human to human transmission of Creutzfeldt-Jakob Disease (CJD)

The 2001 Harvard risk assessment's base case scenario found that out of 1000 simulation runs the mean number of ID50s (infectious doses) available for human consumption would be 35. Almost 11 ID50s (10.9) would be derived from brain and spinal cord. **Twenty (more than half) are derived from AMR products.** (Harvard Risk Assessment, 2001 Section 3.1.2.7 – 3.1.2.9; Appendix 3A Base Case).

We also support and commend the USDA for prohibiting the use of mechanically separated (MS) product for human food.

Identification

McDonalds fully supports the implementation of a mandatory national identification system for cattle. We realize the USDA is working diligently to implement a national cattle identification system, however we urge that a framework be put in place without any further delay. The USDA has previously stated that it would begin to issue premise identification numbers in July. We ask that USDA meet this stated goal.

Identification is essential for efficient and effective disease control and eradication systems. This issue is not limited to BSE. Prevention, control and elimination of highly contagious and vector borne diseases also require identification and recordkeeping systems.

McDonalds is committed to working with the USDA and all sectors of the government to do what it takes to get a traceability system in place as soon as possible.

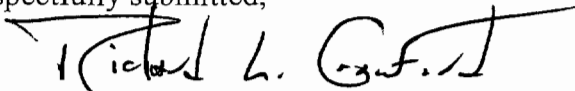
Animal Feed

As stated previously, McDonalds commends the USDA for taking actions to protect public health. However, we feel that there are additional actions needed in regards to the feed ban. The most complete way to assure protection of both the American public and the national herd is to prevent cattle from being exposed to BSE.

Per the 2001 the Harvard Risk Assessment: "Our evaluation of potential risk mitigation actions highlights potential measures to further reduce the already low likelihood that BSE could spread to cattle or contaminate human food if it were to arise. Prohibiting the rendering of animals that die on the farm, possibly of BSE, removes a great deal of potential contamination in the animal feed chain and reduces average predicted cases of BSE following introduction of ten infected cattle by 77%. Implementation of a UK-style ban on specified risk material (*e.g.*, spinal cords, brains, vertebral columns) from both human food and animal feed reduces the predicted number of BSE cases in cattle by 80% and the potential human exposure by 95%."

We realize that the majority of the authority for these actions falls under the jurisdiction of the FDA. We urge USDA to work cooperatively with the FDA to completely remove all SRMs and down and deadstock from the animal feed chain. This was also a recommendation of the International Advisory committee.

Respectfully submitted,



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