September 13, 2004

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USDA, FSIS Docket Clerk 300 12th Street, SW Room 102, Cotton Annex Washington, DC 20250

Re: Docket No: 04-021 ANPR Federal Measures to Mitigate BSE Risks: Considerations for Further Action

04-021ANPR

04-021ANPR-70 Richard L. Crawford

Dear Sir or Madame:

On behalf of McDonald's Corporation, which operates more than 13,000 restaurants in the United States, we appreciate the opportunity to submit comments to this very important Advance Notice of Proposed Rulemaking (ANPRM). 69 Fed. Reg. 42288 (July 14, 2004).

In previous comments submitted to FSIS regarding the removal of SRMs, McDonalds fully supported this rule and its immediate implementation. The removal of SRMs from human food is the primary firewall to protect the US consumer from being exposed to the BSE agent. While we applaud the requirement for SRM removal, we feel that it is equally important for FSIS to insure that each slaughterplant which processes cattle have systems in place which prevent cross contamination between edible tissue and SRMs. This should include but not be limited to the use of separate equipment, such as knives, blades, etc. where appropriate. In addition, it is also important that appropriate and effective disinfection procedures for equipment used to handle SRMs be developed and approved for use.

It is our opinion that requiring SRM removal without a procedure to prevent cross contamination is inadequate as a protective public health measure. The TSE agents (prions) are sticky and highly resistant to disinfection. If SRMs such as brain and spinal cord are allowed to contact equipment and other surfaces such as deboning tables which then are used to handle and process edible tissue this could allow contamination and negates the intention of the ban. This is true not only in plants slaughtering fed cattle both under and over 30 months but also in plants slaughtering predominately older cattle. It is important that measure be taken to prevent cross contamination between carcasses and SRMs in the cull plants. McDonalds requires their suppliers to prevent cross contamination and audits against certain measurable standards such as requiring spinal cord to be removed on the kill floor. We would be willing to share these standards with FSIS as an example.

McDonalds again recommends that dura (the covering around the brain and spinal cord) be added to the list of SRMs. While skull and vertebral column are included as SRMs, dura is not. If dura is not removed 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.

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.

In regards to imported meat products from other countries, McDonalds suggests that no SRM exemption be made for countries based on BSE risk. The long incubation period and limited surveillance in many countries can limit the ability to accurately determine risk. Also, the risk level of a country could potentially change over night if the trading patterns of a country changed. It seems logistically impossible to maintain a system which could continually monitor the world's trading patterns. In addition, science has not provided all of the answers in regards to the transmission of BSE. Requiring SRMs to be removed from imported products for human food is prudent. If the US would wait until disease is confirmed the exposure would already have occurred.

Thank you for the opportunity to comment on these very important issues.

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