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FSIS Docket Clerk  
Docket #03-038IF, Room 102 Cotton Annex  
300 12<sup>th</sup> Street, SW.  
Washington, DC 20250-3700

Dear Sir or Madam,

In a relatively comprehensive Federal Register notice [69 Fed.Reg. 1862-1874 (Jan 2004)], the Food Safety and Inspection Service expanded the organs, tissues and fluids considered "specified risk materials" (SRMs). The Agency is prohibiting SRMs for human consumption due to the risk of poisonous or deleterious substances that may render it injurious to human health. The current restrictions may still allow high-risk tissues to enter the human food supply. The proposed regulations suggested by FSIS are inadequate compared to other international standards. The proposed regulations stipulate the designation of the brain, skull, eyes, trigeminal ganglis, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia (DRG) of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine of all cattle as SRMs. The United States is a leader amongst nations and should continue to uphold the highest of standards in its food and safety policies.

The United States should entail the same level of standards as other problematic nations. Some of these leading countries consist of Japan, Australia/New Zealand, Portugal, Austria and the United Kingdom. These countries are leaders in food and safety protocol concerning BSE. These countries have conducted extensive research and have identified and classified organs, tissues and fluids into four categories according to their potential risk of contamination as seen below (European Commission 2002).

<b>Category I: very high infectivity</b>	Brain, spinal cord, eyes
<b>Category II: high infectivity</b>	Cerebrospinal liquid, hypophysis (pituitary gland), ileum (lower part of the small intestine), lymph nodes, tonsils, spleen, suprarenal gland, upper part of the colon (proximal), dura mater ("hard" meninges), placenta, pineal gland
<b>Category III: moderate infectivity</b>	Bone marrow, liver, lung mucous membrane of the nose, pancreas, peripheral nerves, thymus, lower part of the colon (distal)
<b>Category IV: no detectable infectivity</b>	Blood, mammary glands, ovaries, faeces, foetal tissue, uterus, coagulae, heart, testicles, milk, kidney, seminal vesicle, thyroid gland, serum, skeletal muscles, saliva, salivary glands, connective tissue, gall bladder, hair, skin, bones, cartilage tissue, urine

The proposed list by FSIS consists of category I materials but does not include all items that have been identified as category II (high infectivity) or items that are located in close proximity to category I organs. In addition to high infective organs, bone marrow (Category III) needs to be investigated as a SRM.

### **Bone Marrow Infectivity**

A pathogenetic study at the Veterinary Laboratory Agency has diagnosed infectivity in bone marrow of cattle. This and other studies identify bone marrow as a potential health threat to humans. According to the FMIA statute 21 U.S.C. 601 (m) (1) bone marrow is considered an adulterated food product since research has proven that infection of the BSE agent is possible in bone marrow.

### **Organs Located in Close Proximity to Category I Organs**

The parts of the cattle known to carry the infectious agent that can cause BSE include the spinal cord, brain and retina that are included in the SRMs list. However, the dura mater, hypophysis, pineal gland and cerebrospinal fluid are all located within close proximity of the SRMs, which increases the chance of contamination during processing. The Commission of the European Communities places the dura mater, hypophysis and pineal gland in category II only if contamination with brain tissue can be avoided (European Commission 2002). AMR systems have been responsible for contaminating low risk tissues with high-risk tissue and therefore, FSIS can not guarantee security against contamination of our nation's food supply. These organs that are located close to "specified risk materials" should be prohibited in the human food chain.

Britain has identified the potential hazard and has banned "beef on the bone," for example, T-bone steaks to protect consumers from BSE contamination. The "T" in a T-bone steak is a vertebra from the animal's spinal column, and as such may contain a section of the actual spinal cord. Such a ban in the United States would mirror the recommendation of the World Health Organization, as well as the ban implemented by the British government (World Health Organization 1999).

### **Spleen and Pancreas Infectivity**

The UK and Portugal have designated the spleen and pancreas as SRMs since they are infectious long before clinical signs are visible in nerve and brain tissue. The infection quickly multiplies in the lymphoreticular system where it undergoes amplification. This information should be highly regarded when FSIS amends its current SMR list.

## **Conclusion**

In summary, FSIS must fully consider the consequences of its policymaking proposal on the quality of human health. In the interest of the public the current policies of FSIS are inadequate and further evaluation of all items listed as category II, organs located close to category I organs and bone marrow should be assessed in order to create a thorough SRMs list. The list also does not adhere to recommendations by the World Health Organization stating that countries should not permit tissues that are likely to contain the BSE agent to enter any food chain, human or animal. When devising the final SRMs list FSIS should examine policies in other infected countries and take a cautious approach since human lives are at risk.

Sincerely,

A handwritten signature in cursive script that reads "Tammy K. Roberson". The signature is written in black ink and is positioned below the word "Sincerely,".

Tammy K. Roberson

### Works Cited

BSE Risks. 11 Jan. 2002. European Commission. 24 Mar. 2004

WHO infection Control Guidelines for Transmissible Spongiform Encephalopathies. 26

Mar. 1999. World Health Organization. 26 Mar. 2004