The Follow-up to the Beef AMR Product Survey of 2002:

Follow-up Results and Actions for the Elimination of CNS (Spinal Cord) Tissues from AMR Products Derived from Beef Vertebrae

Introduction:

Advanced Meat/Bone Separation and Meat Recovery (AMR) systems are designed to remove the attached skeletal muscle tissue from livestock bones without breaking or crushing the bones. This machinery separates meat by scraping, shaving, or pulling the muscle tissue away from the bone. However, unlike traditional mechanical separation, AMR machinery cannot break, grind, crush or pulverize bones to recover muscle tissue. Bones must emerge essentially intact and in natural physical conformation. The AMR process is used to produce meat from beef and pork carcasses.

FSIS policy gives a clear definition of "meat" that does not include spinal cord tissues. Therefore, meat products containing spinal cord tissues are misbranded and possibly adulterated. In December 2002, FSIS issued a directive requiring that routine regulatory samples be taken in beef plants using AMR systems with vertebral columns to ensure that spinal cord tissues are not present in the AMR products. The following survey was conducted in order to determine a baseline for the presence of spinal cord tissues in AMR products derived from beef vertebral columns. The results will guide FSIS in determining whether establishments are preventing spinal cord tissues from being mixed with beef.

USDA’s definition of meat was amended in December 1994 to include products from advanced meat/bone separation and meat recovery systems. Meat derived from this method is to be comparable in texture and composition to meat trimmings and similar to hand-deboned products so it does not require special labeling. AMR product is labeled as "meat" on product labeling (i.e., "beef," "pork," "beef trimmings," etc.). Since spinal cord tissues falls outside the definition of "meat," product produced using AMR systems cannot contain spinal cord tissues.

Before the directive was issued in December 2002, FSIS inspectors used visual inspection of an establishment’s

entire AMR system operation to conduct regulatory sampling of AMR products. Inspectors would take regulatory samples of AMR products when they believed that the establishment was not adequately removing the spinal cord. The 2002 directive requires them to take routine regulatory samples to ensure that spinal cord is being properly removed.

The directive specifically requires inspection personnel to notify the establishment at the time they take a sample, allowing the establishment to hold the product being tested. If the test identifies the presence of spinal cord tissues, then inspection personnel will withhold marks of inspection from the establishment's AMR product and tag the AMR system itself, meaning neither the product nor the equipment can be used until satisfactory corrective action has been taken.

If the establishment has distributed the sampled product, then FSIS will request a voluntary recall on the basis that the product is misbranded. If the establishment has not distributed the sampled product, then inspection personnel will verify any action taken to correct the problem, such as re-labeling the product to meet FSIS regulations for mechanically separated product or diverting it into rendering.

Inspection personnel will conduct follow-up sampling to verify that the establishment has taken appropriate corrective action. AMR production will not be allowed to resume until FSIS determines that corrective actions have been successful.

Findings:

There was a wide range of results in the recently conducted survey. Some plants produced AMR products 100% free of central nervous system (CNS) tissues. Others, however, clearly had a problem keeping CNS (spinal cord) tissues out of their AMR products.

In fact, about 26 percent (9 of 34) of the establishments tested in the AMR Survey of 2002 had negative laboratory results for CNS tissues in their final beef AMR products.

However, about 74 percent (25 of 34) of the establishments tested in the AMR Survey of 2002 had positive laboratory results for CNS tissues in their final beef AMR products.

The AMR products were derived from beef vertebra, using 42 AMR systems in 34 establishments. There were 394 AMR product samples tested. The within-establishment prevalence of AMR samples testing positive for CNS tissues ranged from 16.7 percent (one positive of six tested samples) to 75 percent (three positive of four tested samples). Additional details are in the draft of the final report of the AMR Survey of 2002.

The summary of the follow-up results of the AMR Survey of 2002 is as follows:

1. 100 percent (25 of 25) of the IICs of establishments with CNS positive results in the AMR Survey of 2002 were asked one or more times by their respective District Office Inspection Coordinator (IC) to perform unscheduled performance-based inspection system (PBIS) procedure code 04A03. This PBIS procedure code is for verification of the AMR process that produces AMR products derived from meat trimmings and bones (vertebral and non-vertebral) containing tags of skeletal muscle. This is the established protocol of the AMR Survey for within-establishment follow-up of AMR survey samples that tested positive to CNS tissues.

2. About 92 percent (23 of 25) of the establishments with CNS positive results in the AMR Survey of 2002 submitted 68 follow-up AMR samples for PBIS procedure code 04A03 verification. The distribution of submitted follow-up AMR samples by establishments is:

   10 establishments submitted 1 follow-up sample

   6 establishments submitted 2 follow-up samples

   5 establishments submitted 3 follow-up samples

   1 establishment submitted 12 follow-up samples

   1 establishment submitted 19 follow-up samples

3. About 33 percent (22 of 67 tested) of the follow-up AMR samples were positive for CNS tissues. One AMR sample was discarded for being "out of condition" or putrefied on arrival at the laboratory.

4. About 35 percent (8 of 23) of the establishments submitting follow-up AMR samples tested positive for CNS tissues in their AMR follow-up samples.

5. Follow-up AMR samples are submitted to the FSIS Eastern Laboratory (Athens, Georgia).

6. For calendar year 2002 (of non-compliance reports (NRs) received for analysis), 18 NRs were written for non-compliant AMR products (submitted regulatory samples) derived from beef vertebrae that tested positive for CNS tissues independent of the survey. All of the received NRs referenced PBIS procedure code 04A03, except three NRs that referenced respectively PBIS procedure codes 03C02, 04B01, and 04B03. For calendar year 2002 (of NRs received for analysis), one NR was written for non-compliance on verification of PBIS procedure code 04A03 for the production of AMR products derived from beef vertebrae. Visible spinal cord was discovered in the AMR system. Regulatory AMR samples were not submitted. In summary, for calendar year 2002 (of NRs received for analysis), seven establishments received 19 NRs: one establishment received six NRs, one establishment received five NRs, one establishment received three NRs, one establishment received two NRs, and three establishments received one NR each. One establishment should have had a NR written for non-compliant AMR product that tested positive for CNS (spinal cord) tissues. About 92 percent (24 of 26) of the establishments sent their non-compliant (for the presence of CNS (spinal cord) tissues) AMR products to inedible rendering or condemned the non-compliant AMR products.

7. For calendar year 2002, establishments have taken numerous actions for increasing the probability of eliminating CNS tissues from their AMR products.

- Two establishments discontinued their use of functioning AMR equipment.

- One establishment discontinued its use of AMR equipment when it was damaged by a piece of metal and then not repaired.

- Establishment employees were trained and re-trained to remove spinal cords from vertebral columns.

- Mis-split vertebral columns were identified with food-safe colored dye (typically blue food dye) for removal of entrapped spinal cord in the vertebral column before being used to produce AMR products, or for elimination of the entire vertebral column from the AMR process.

- Hand-operated tools were added, i.e., scrapers to remove spinal cord and surrounding materials of the spinal canal, and various power-driven cutters to groove the spinal canal to remove any spinal cord and surrounding material. The removed materials typically were collected by vacuum to an enclosed vessel. Several types of power-driven cutters were used. One power-driven tool was a Jarvis saw with vacuum (Jarvis Products Corporation, Middletown, CT) that works as a mechanically cutting router to remove tissues over the length of the opened vertebral canal of the vertebral columns. Another similar power-driven tool was a Whizard trimmer (Bettcher Industries, Inc., Vermilion, OH).

- Additional establishment labor was employed to check vertebral columns for the presence of spinal cord, and then to remove the spinal cord tissues or discard the vertebral column. In some establishments, the spinal cord and its covering or sheath (dura mater) were removed.

- In one establishment, a wash station was installed prior to the carcass wash station, for additional removal of the spinal cord and sheath from the vertebral column.

- One establishment installed a device that stabilized or held the hanging split carcass (half) while the spinal cord was removed from its spinal canal.

- An establishment implemented a “closer” inspection for the removal of spinal cord on the kill floor. (Note: later the establishment eliminated a CCP, because of several HACCP CCP deficiencies to limit (zero tolerance) spinal cord tissues in vertebrae located at the beginning of the AMR system!).

- Another establishment established a HACCP CCP with a zero tolerance limit of spinal cord tissues in the spinal canal of the carcass half (located on the kill floor).

- An establishment installed rapid testing equipment to test for the presence of CNS tissues in their AMR products. An AMR products testing program was implemented. Further, private laboratory testing for the presence of CNS tissues was increased after finding positive results for the presence of CNS tissues.

8. For calendar year 2002, about 92 percent (24 of 26) of the establishments sent their non-compliant (for the presence of CNS (spinal cord) tissues) AMR products to inedible rendering or condemned the non-compliant AMR products. The remaining 8 percent (2 of 26) of the establishments are known to have re-labeled some of their non-compliant AMR products derived from beef vertebrae as mechanically separated beef (MS(Beef). The AMR products were non-compliant because the AMR products tested positive for spinal cord (CNS) tissues. The MS (Beef) was sold for further processing (i.e., chili). It is permissible to re-label if the conditions of the regulatory requirements are met and that spinal cord is expected as a component of this material. It was assumed that the conditions were met, based on actions of inspection program personnel that referenced FSIS regulations (9 CFR 318.18, 318.24, 319.5, 319.6, and 319.15).

9. The regulatory requested sampling program for AMR products derived from beef vertebra began the first week of March 2003. The Eastern Laboratory is using their modified immunohistochemical procedure to detect CNS (spinal cord) tissues in AMR products derived from beef vertebrae. Currently, the optimum level of this testing procedure for the Eastern Laboratory is about 100 to 110 samples per week, or about 20 to 22 samples per workday. Initially, all AMR systems producing AMR products derived from beef vertebrae will be randomly tested for CNS tissues at least once every three weeks. Relatively riskier establishments for the presence of CNS (spinal cord)

tissues in their AMR products derived from beef bones can be expected to be sampled more frequently than those determined to be relatively less risky.

10. During the summer of 2002, Townsend Engineering of Des Moines, Iowa, sponsored a one-day demonstration of one of their models of Protecon AMR systems for the production of AMR products derived from beef vertebrae. This demonstration was conducted at Iowa State University at Ames, Iowa. AMR products were produced from feedstock vertebral columns that had been mechanically pre-processed (physical treatment by a cutting and vacuum removal of material of the spinal canal) by a particular type of hand-held power-driven tool. This power tool was used at a participating establishment for the removal of CNS (spinal cord) tissues and adjacent tissues of the spinal canal of the vertebral column. The control was vertebrae that received no special treatment or pre-processing preparation, or had spinal cords removed by hand at a participating establishment. A representative of the FSIS Eastern Laboratory (Athens, Georgia) collected composite AMR product samples from each of the treatments and the control. The FSIS Eastern Laboratory tested the AMR product samples for the presence of CNS (spinal cord) tissues, using their immunohistochemical procedure. Subsequently, the FSIS test results were found to be negative for CNS (spinal cord) tissues in all of the collected AMR product samples of the treatments and the control. Therefore, FSIS found no difference for the presence of CNS tissues between all of the treatments of feedstock beef vertebrae and the control. Also, AMR product samples of the treatments and the control were collected and sent to the University of California Davis for analysis. The results of the UC Davis analysis have not yet been reported to FSIS.