**Tyson Fresh Meats, Inc.**

Case Ready
Tyson Fresh Meats, Inc.
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Dakota Dunes, SD 57049

July 25, 2005

FSIS Docket Clerk
Docket No. 04-042N
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 102, Cotton Annex Building
300 12th Street SW
Washington, DC 20250-3700

04-042N
04-042N-2
Brian McFarlane



**Re: Docket No. 04-042N "HACCP Plan Reassessment for Mechanically Tenderized Beef Products"**

To Whom It May Concern:

Tyson Foods, Inc. would like to express appreciation for the opportunity to comment on the May 26, 2005 issuance of Docket No. 04-042N – HACCP Plan Reassessment for Mechanically Tenderized Beef Products. The document detailed the need for facilities that produce non-intact (needle tenderized/enhanced) beef products to consider three recent recalls associated with *Escherichia coli* O157:H7 (ECH7). Subsequently on June 1, 2005 USDA FSIS distributed Notice 32-05 that stated when inspection personnel verify the 2005 reassessment they are to confirm that the establishment has evidence that it considered the potential hazard of ECH7 as part of the hazard analysis or HACCP plan. With consideration of these documents and the information contained within, Tyson Fresh Meats (TFM) recognizes the need to reevaluate current HACCP plans and food safety systems that pertain to needle tenderized/enhanced products.

Regarding the notices, there are several considerations that need to be taken into account.

## RAW MATERIALS

When beef carcasses actually get contaminated with ECH7, it is typically with a very few number of cells. Koohmaraie *et al.*, 2003, reported that only 1.2% of beef carcasses even have ECH7 present post-intervention and 100% of these carcasses had less than 3 cells per 100 $cm^2$. With 75% of the surface of the beef carcasses being removed during the fabrication process, there is a very low likelihood that any ECH7 cells would actually remain on the primals. There are several studies that found no ECH7 on beef subprimals. In 2004, the National Cattlemen's Beef Association (NCBA) reported NO (zero) ECH7 in two studies evaluating a total of 1,199 beef subprimal. Tyson Fresh Meats conducted a study in 2004 that revealed NO (zero) ECH7 on 407 beef subprimals. With the existing subprimal prevalence data, we believe this negates the need for verification testing on primals in case ready facilities.

The internal portions of beef cuts are generally regarded as being sterile. It has been reported that when beef primals are inoculated with 5 or more logs of ECH7, even at these unrealistically high levels, blade tenderization only transfers 3 to 4% of the surface contamination to the interior of the muscle (Sporing, 1999) and needle enhancing only transfers 4 to 8% (Lambert *et al.*, 2001). These studies went on to show that when cells are translocated, it is only to a depth of 6 mm or ~¼ inch. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) similarly reported that when ECH7 was present, only 0.02% of the subsequently needled products had any internal presence of ECH7 and most

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only had one cell. Additionally, the CDC reported that the infective dose for ECH7 in daycare and nursing home settings is believed to be similar to that of Shigella spp. of around 10 cells (Foodborne Pathogenic Microogranisms and Natural Toxins Handbook, 1/4/2005). Thus even if the maximum percentage of translocation that has been reported occurs on the typical number of cells that are present, the resulting product would not even have the minimal number of cells to be considered infective.

The Docket suggests facilities should adopt a supplier prerequisite program for raw materials. One of the requirements of this program should be a thermal or equivalent intervention. Combining these requirements with the prevalence data referenced above, it can be concluded that the hazard of ECH7 on primals is *not* reasonably likely to occur at the point of receipt in facilities that tenderize or needle inject beef products.

**INJECTION/ENHANCEMENT**

Even with the extremely low chance of actually having viable ECH7 cells present and then being translocated to just under the surface of the product during tenderizing or injecting, the most important factor in preventing ECH7 amplification is temperature control. Temperatures throughout the entire facility from raw material receiving, injection, to finished product storage and shipping must be controlled. To verify that the temperatures of the two critical components, raw materials and marinades, have been maintained, the internal temperature of enhanced products after injection can be monitored. Acceptable temperatures at this point in the process will give assurance that temperature controls have been maintained and ECH7 amplification has been prevented.

**SANITATION**

The Docket referenced three recalls; one of which specifically detailed the "*lack of*" adequate sanitation procedures which allowed for widespread growth and distribution of ECH7 throughout the system and reoccurrence from day to day. These previous recalls support our belief that proper sanitation and best practices are one the most important components preventing a pathogenic outbreak. Facilities producing blade tenderized or needle injected beef products should have sound GMP's for marinade temperature control, needle rotation and cleaning, injector and associated equipment sanitation, and pre-operational sanitation verification. The combined benefits of proper temperature controls and good sanitation practices will prevent ECH7 amplification. Many of these same focal points have been identified in the "*Industry Best Practices for Pathogen Control during Tenderizing/Enhancing of Whole Muscle Cuts*" which was produced by the National Cattlemen's Beef Association (NCBA), American Meat Institute (AMI), National Meat Association (NMA), and Southwest Meat Association (SMA) in March of 2005. This report also identified raw material supplier requirements, temperature and process controls, and good sanitation programs as important components to a tenderization or injection process.

**COOKING**

The absolute measure of food safety protection to the consumer is the endpoint cooking temperature. The Docket specifically points out that manufacturers of blade tenderized/needle enhanced beef products need to consider including cooking instructions in addition to required safe handling instructions. The NACMCF also suggests that adequate cooking instructions should be on all raw beef products, not just non-intact and tenderized products. Luchansky, 2004 and Phebus *et al.*, 2000 showed that cooking to a minimum internal temperature of 140°F is all that is needed for thermal destruction of ECH7 in blade tenderized/needle enhanced beef products. Franken *et al.* (2004) surveyed the cooking methods of five

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hundred individuals throughout seven states and found that 96% of the participants cooked steaks to a degree of doneness at or above 145°F.

## CONCLUSION

Research has shown that the multiple hurdle interventions that beef processors have implemented over the last five+ years in slaughter and fabrication facilities has reduced ECH7 prevalence to extremely low or non-detectable levels on beef sub-primals. There are many studies and reports documenting that the industry is literally dealing with only a few cells when present and the frequency of ECH7 is dwindling each year. This continual decline in ECH7 is strongly supported by the FSIS trim sampling program results. We believe that the combination of supplier prerequisite programs, sanitational best practices, and temperature controls are the most critical areas to manage. We also believe that, these associated programs should be developed by the respective producer of non-intact products due to the need to individualize them for each facility. As the industry leader, Tyson Fresh Meats, Inc. is addressing the concerns raised by FSIS in addition to utilizing previously self imposed measures as well as a continual improvement approach to insure the food safety of non-intact beef products produced in our facilities.

Sincerely,

Brian McFarlane

Brian McFarlane
Director of Research & Development and FSQA
Tyson Fresh Meats, Inc.