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ESCHERICHIA COLI O157:H7 REASSESSMENT SCENARIO

THIS SCENARIO WAS DEVELOPED BY THE AMERICAN ASSOCIATION OF MEAT PROCESSORS (AAMP) TO ASSIST THE AAMP MEMBERSHIP AS THEY REASSESS THEIR HACCP PLANS IN RESPONSE TO THE FOOD SAFETY AND INSPECTION SERVICE (FSIS) NOTICE 65-07 NOTICE OF REASSESSMENT FOR ESCHERICHIA COLI O157:H7 CONTROL AND COMPLETION OF A CHECKLIST FOR ALL BEEF OPERATIONS.

BACKGROUND

AAMP Meat Processing Inc. is ***hypothetical*** very small meat processing establishment located in Elizabethtown, PA. It slaughters ten cattle each week under Federal Inspection that it purchases from a local sale barn. It makes as a variety of meat products that include ready-to-eat (RTE) processed meat products (e.g., *summer sausage, snack sticks, BBQ beef, etc.*), ground beef (e.g., bulk and patties), steaks, and roasts. As a part of the business, AAMP Meat Processing Inc. also has a retail store located in the same building to sell meat products to the general public, as well a few local restaurants.

AAMP Meat Processing Inc. typical only slaughters cattle every Tuesday. On Monday, Wednesday, and Thursday they process under Federal Inspection. Typically on Friday, they process under retail exemption to prepare for the weekend's retail sales.

While AAMP Meat Processing Inc. fabricates its own beef carcasses, due to customer demand it must also purchase beef raw materials (i.e., beef primal cuts, boneless beef trimming, etc.) to satisfy customer demands. The purchased beef raw materials are fabricated into steaks, roast, and ground beef. Most all of the purchased product is utilized through the retail exempt store and most all of the beef carcasses are sold as federally inspected meat products.

Due to a HACCP plan reassessment in 2003 that addressed if *E. coli* O157:H7 was reasonably likely to occur as a food safety hazard, AAMP Meat Processing Inc. implemented the following purchase specification for beef products purchased from other USDA inspected establishments:

Pre-Requisite Program for Purchasing Beef For Use In Raw, Not Ground HACCP Plan (Beef) & Raw, Ground HACCP Plan (Beef)

Beef purchased by AAMP Meat Processing Inc. for use in our products will be required to meet our purchase specifications as outlined below:

- AAMP Meat Processing Inc. only purchases beef from suppliers that are USDA inspected, in which every box is labeled with the USDA Mark of Inspection (i.e., "USDA Inspected and Passed"). Therefore, every shipment is in compliance with USDA regulations and requirements prior to its arrival at AAMP Meat Processing Inc..
- A yearly letter will be obtained from suppliers stating what the supplier is doing to eliminate or reduce *E. coli* O157:H7 to undetectable levels and that the supplier is in compliance with FSIS regulations regarding *E. coli* O157:H7.

HACCP PLAN REASSESSMENT

Prior to this reassessment, AAMP Meat Processing Inc. reassessed its HACCP plans on an annual basis in accordance to FSIS regulations. Due the recent release of FSIS Notice 65-07, AAMP Meat Processing Inc. has reassessed the following HACCP plans by October 26, 2007:

- Beef Slaughter HACCP Plan
- Raw, Not Ground HACCP Plan (Beef)
- Raw, Ground HACCP Plan (Beef)

Although a reassessment is mandated to be accomplished by October 26, 2007, a HACCP plan reassessment does not always mean that a change is needed of the establishment's current HACCP plan. Minor changes have been incorporated into the establishment's HACCP plan in an attempt to incorporate interrelated *E. coli* O157:H7 contamination controls throughout production. The following is a description of how AAMP Meat Processing Inc. manages its prerequisite program to verify that *E. coli* O157:H7 has been controlled, reduced, or eliminated.

BEEF - BEEF SLAUGHTER HACCP PLAN

AAMP Meat Processing Inc. utilizes a hurdle approach to control *E. coli* O157:H7 contamination throughout the cattle slaughter process:

1. They attempt to purchase relatively clean cattle from the local sale barn. The cattle are purchased on Monday and brought to the establishment for slaughter on Tuesday morning.
2. After slaughter, but prior to FSIS inspection, the carcasses are trimmed to remove any visible contamination. *This step is a CCP for zero tolerance for fecal material, ingesta, and/or milk.*
3. After FSIS personnel perform their final inspection of the carcass, the carcasses are rinsed with warm water for at least 2 minutes (nozzle is generally no more than one foot from the carcass surface).
4. The carcasses are rolled into the carcass chilling cooler to allow excess water to drip from the carcass for at least five minutes (this step ensures that the antimicrobial rinse makes better contact with bacteria on the carcass surface).
5. After five minutes of drip time, establishment personnel spray the carcasses with 2% lactic acid using a garden type sprayer (sufficient lactic acid is applied on the carcass such that some of it drips off). *This step is a CCP for the evenly sprayed application of an antimicrobial to each beef carcass, heart, liver, and tongue. The antimicrobial solution is applied according to manufactures specifications and the establishment's supporting documentation. It is also in compliance with the limits outlined within FSIS Directive 7120.1 (Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products).*

As with any federally inspected establishment, AAMP Meat Processing Inc. takes 13 sponge samples for its generic *E. coli* testing program which will begin the first full week after June 1, 2008 and is scheduled to end August 31, 2008 (*if the slaughter schedule remains consistent*). Previous history has demonstrated that its beef slaughter process has been effective in preventing fecal contamination. Test results have meet the criteria in the regulations and provide management evidence that AAMP Processing Inc. is maintaining adequate process control for fecal contamination and sanitary dressing.

It is known by AAMP Meat Processing Inc. that this generic *E. coli* testing verifies that the beef slaughter process control systems are working as intended to prevent fecal contamination, the primary avenue of contamination for harmful bacteria. Test results that meet the criteria in the regulations provide evidence that AAMP Meat Processing Inc. is maintaining adequate process control for fecal contamination and sanitary dressing. It is also understood that to completely address the issue of any *E. coli* O157:H7 contamination and verification, the establishment must test specifically for *E. coli* O157:H7, not generic *E. coli*.

October 26, 2007 HACCP Reassessment Additions

Although no beef carcasses are shipped out of the establishment as whole carcasses, to be more proactive, AAMP Meat Processing Inc. will also implement a new *E. coli* O157:H7 testing program of the beef carcasses. Since AAMP Meat Processing Inc. slaughters such a minimal amount of cattle, the establishment will swab a carcass for *E. coli* O157:H7 contamination quarterly (at least once every 3rd month - 4 times annually). This *E. coli* O157:H7 testing program will verify the

establishment's multiple intervention strategies are properly working. When testing beef carcasses, AAMP Meat Processing Inc. will hold the beef carcass (*either as a whole carcass or fabricate the carcass and hold all beef materials*) until the sample results are known.

When a beef carcass is tested, each carcass will be considered a lot. Therefore, if AAMP Meat Processing Inc. takes an *E. coli* O157:H7 sample of one carcass and it comes back positive, it must address the *E. coli* O157:H7 contamination on that one tested beef carcass (*i.e.*, two beef carcass sides); not all of the beef carcasses derived from cattle slaughtered during that production day.

BEEF - RAW, NOT GROUND HACCP PLAN

As stated previously, AAMP Meat Processing Inc. fabricates its own beef carcasses and purchases beef raw materials (*i.e.*, beef primal cuts, boneless beef trimming, etc.). Prior to the October 26, 2007 reassessment the establishment relied solely on supplier purchase specifications and FSIS *E. coli* O157:H7 testing of its ground beef product.

October 26, 2007 HACCP Reassessment Additions

AAMP Meat Processing Inc. is in compliance with all USDA/FSIS regulations. As a result from the October 26, 2007 HACCP Reassessment, the establishment has included the following statement within its pre-requisite program for purchasing beef:

- Suppliers will be contacted quarterly to ensure the interventions are being conducted and the intervention methods have not changed. This contact will be recorded in a log, including the date, time of contact, the person contacted, title/position of the person contacted, and the status of their methods (Attachment #1). This will serve as AAMP Meat Processing Inc. verification of the *E. coli* O157:H7 interventions have been met at supplier establishments.
- The supplier will immediately notify the HACCP Coordinator or Plant Management of AAMP Meat Processing Inc. if its interventions have been ineffective or not appropriately applied.
- The supplier must have CCP's addressing *E. coli* O157:H7 and verification of the testing conducted for the pathogens.

Beef raw materials purchased include (but not limited to) such beef primal cuts as whole beef rib (NAMP 109, 112), beef inside round (NAMP 169), beef bottom round (NAMP 170), beef short loin (NAMP 174), beef strip loin (NAMP 180), beef top sirloin butt (NAMP 184), and beef tenderloin (NAMP 189), as well as some other miscellaneous beef items.

AAMP Meat Processing Inc. does not blade tenderize or moisture enhance any beef products.

Any beef trimmings that are generated from the fabrication of any beef products purchased from suppliers (*i.e.*, bench trim) are consolidated in well defined lotting system. After enough bench trim is consolidated, AAMP Meat Processing Inc. will then determine how to utilize the raw beef material. The establishment will either:

- Grind the beef bench trim as a lot and then incorporate that into an *E. coli* O157:H7 testing program.
- Divert beef bench trim to the production of a fully-cooked, RTE processed meat product that has validated lethality step adequate to effectively address *E. coli* O157:H7 (*i.e.*, a further cooking step).

AAMP Meat Processing Inc. will not be testing any beef trim components (generated by the fabrication of beef carcasses or beef primal cuts purchased from suppliers). Management feels as though the testing of beef trim components for *E. coli* O157:H7 contamination is not a logical testing protocol. This was determined as AAMP Meat Processing Inc. has an established an *E. coli* O157:H7 testing program for the production of ground beef. It is not logical to test beef trim components destined for ground beef, when an *E. coli* O157:H7 testing program is already established when ground beef is produced. AAMP Meat Processing Inc. does not sell any beef trim components to anyone.

BEEF - RAW, GROUND HACCP PLAN

As stated previously, AAMP Meat Processing Inc. fabricates its own beef carcasses and purchases beef raw materials (*i.e.*, beef primal cuts, boneless beef trimming, etc.). Prior to the October 26, 2007 reassessment the establishment relied solely on supplier purchase specifications and FSIS *E. coli* O157:H7 testing of its ground beef product.

October 26, 2007 HACCP Reassessment Additions

AAMP Meat Processing Inc. is in compliance with all USDA/FSIS regulations. As a result from the October 26, 2007 HACCP Reassessment, the establishment has made minor adjustments with regard to the production of ground beef.

Beef trim components generated from cattle/carcasses that were previously slaughtered by AAMP Meat Processing Inc. will not be commingled with any purchased beef trim components during the production of ground beef. This will ensure that *E. coli* O157:H7 contaminated beef components can be traced back to its original source and management expects USDA/FSIS to hold the supplier responsible for the contamination.

AAMP Meat Processing Inc. has revised its lotting protocol to include recommendations outlined with the Kansas State University document titled "*Developing Product Lotting and Coding Systems for Small Meat and Poultry Processing Operations*" (Attachment #2).

Starting November 1, 2007, AAMP Meat Processing Inc. will implement a new *E. coli* O157:H7 testing program. This new testing program will test ground beef that was produced from cattle/carcasses slaughtered and fabricated by AAMP Meat Processing Inc. Since the establishment produces less than 1,000 pounds daily, it will perform an *E. coli* O157:H7 test quarterly (at least once every 3rd month - 4 times annually). This testing rate was determined by Dr. Engeljohn and provided to the American Association of Meat Processors as **draft** breakout scheme (Attachment #3).

Also, starting November 1, 2007, AAMP Meat Processing Inc. will implement a new *E. coli* O157:H7 testing program that will test ground beef that was produced from beef (*i.e.*, beef trim components, bench trim, etc.) purchased from suppliers. Since the establishment produces less than 1,000 pounds daily, it will perform an *E. coli* O157:H7 test quarterly (at least once every 3rd month - 4 times annually). This testing rate was determined by Dr. Engeljohn and provided to the American Association of Meat Processors as **draft** breakout scheme (Attachment #3). AAMP Meat Processing Inc. will attempt to test ground beef produced from beef supplied by each supplier within the quarterly *E. coli* O157:H7 testing program. The establishment will be randomly testing ground beef produced from beef trim components purchased from suppliers and in an effort to ensure an easier *E. coli* O157:H7 testing program, it will attempt to limit the suppliers that beef is purchased from.

When a ground beef sample is taken for *E. coli* O157:H7 testing, AAMP Meat Processing Inc., will hold the tested lot/product while test results are pending (Attachment #4). This methodology has proven to be a good business practice. The test and hold protocol will prevent products from entering commerce that have pending test results for pathogens or other adulterants, which should then greatly reduce the potential risk associated with positive results. Effective practices for identifying and holding products will be used when the establishment conducts testing and when USDA/FSIS or another government agency takes a sample. AAMP Meat Processing Inc. works with customers to ensure that the product can be held pending the test result. If the test results as a positive *E. coli* O157:H7 contaminated sample and establishment management will determine the potential disposition of the defined lot.

AAMP Meat Processing Inc. will work with inspection personnel to establish a ground beef *E. coli* O157:H7 testing protocol that achieves the Agency's goal, while not hindering the establishment's meat production. Before collecting samples, FSIS inspection program personnel are to notify the establishment management that they will be collecting a ground beef sample for *E. coli* O157:H7 testing. It is well known by both FSIS personnel and establishment management that the Agency officials are to provide enough time for the establishment to hold the sampled lot.

AAMP Meat Processing Inc. *E. coli* O157:H7 testing will occur at the same time FSIS personnel take a sample for *E. coli* O157:H7 testing. This sampling protocol was determined for several reasons:

1. If *E. coli* O157:H7 sampling is performed in conjunction with FSIS sampling, the establishment reduces the amount of product that will be held in accordance to its test and hold protocol.
2. Since AAMP Meat Processing Inc. is a very small establishment with a limited number of employees and continually busy, testing the same time as FSIS will reduce the likelihood that an *E. coli* O157:H7 test will be forgotten.
3. According to FSIS Notice 66-07 (*Multiple Follow-Up Sampling After FSIS Positive Escherichia Coli (E. Coli) O157:H7 Results*), "if the establishment held the product sampled (or maintained control of the product) pending its own test results, and FSIS and the establishment both found the product positive for *E. coli* O157:H7, FSIS inspection program personnel are not to issue a noncompliance record (NR)."
4. FSIS *E. coli* O157:H7 testing is a part of a surveillance system of the meat industry, while AAMP Meat Processing Inc. *E. coli* O157:H7 testing is a verification activity.

AAMP Meat Processing Inc. expects to closely work with FSIS inspection personnel to ensure that there is an equal distribution of *E. coli* O157:H7 testing ground beef:

1. Ground beef derived from cattle/carcasses slaughtered and fabricated at AAMP Meat Processing Inc.
2. Ground beef derived from beef components purchased from other USDA inspected establishments

While AAMP Meat Processing Inc. does not rely solely on FSIS *E. coli* O157:H7 testing results, the establishment will utilize FSIS *E. coli* O157:H7 testing results as supporting documentation of its food safety system.

When a ground beef sample is taken for *E. coli* O157:H7 testing, AAMP Meat Processing Inc. reserves the right to stop production, perform complete clean up and sanitation procedures, document such sanitation activities, switch beef component source materials, and continue to produce ground beef. All source materials within the same identifiable lot that was tested for *E. coli* O157:H7 contamination will be held until the test result is received. By switching beef component source materials the establishment can continue to produce ground beef while limiting its potential risk associated by a positive test result.

When any ground beef *E. coli* O157:H7 sample is taken (either by AAMP Meat Processing Inc., USDA/FSIS, or another government agency) the establishment will collect the following information regarding the source materials used in the production of the ground beef (Attachment #5):

1. Date and time of production
2. Name of the supplying establishment and contact information of supplying establishment (address, phone number and fax number)
3. Identifiable lot codes of the beef trim components
4. Identifiable lot code of AAMP Meat Processing Inc.
5. Signature of the establishment management or HACCP coordinator

AAMP Meat Processing Inc. has included the following statement within its pre-requisite program for purchasing beef:

- If AAMP Meat Processing Inc. conducts product testing and the test results in a positive test result, the establishment will discontinue buying from that supplier, or will contact the supplier so that the supplier can determine what control measures have failed. If the supplier makes appropriate changes to its controls or interventions so that the supplier could justify that it had effectively eliminated *E. coli* O157:H7, the establishment could continue purchasing from that supplier.

RETAIL EXEMPTION REGULATIONS

AAMP Meat Processing Inc. is in compliance with all USDA/FSIS regulations which include the regulations of retail exemption (Title 9 of the Code of Federal Regulations – Section 303.1). The establishment reserves the right to produce ground beef as retail exempt. Under 9 CFR 303.1(d)(2)(iii)(c), “*only federally or State inspected and passed product is handled or used in the preparation of any product.*” Retail exemption requires no further product testing. To limit the exposure to the potential *E. coli* O157:H7 contamination issue, AAMP Meat Processing Inc. will only use ground beef components from other USDA inspected establishments.

When any ground beef is produced under retail exemption, the establishment will collect the following information regarding the source materials used:

1. Date and time of production
2. Name of the supplying establishment and contact information of supplying establishment (address, phone number and fax number)
3. Identifiable lot codes of the beef trim components
4. Identifiable lot code of AAMP Meat Processing Inc.
5. Signature of the establishment management or HACCP coordinator

AAMP Meat Processing Inc. understands that retail exemption does not completely remove the possibility of getting ground beef tested for *E. coli* O157:H7 contamination. The Agency can still purchase ground beef product and test it for *E. coli* O157:H7 contamination. If ground beef were to be purchased and tested for *E. coli* O157:H7, the establishment requires that the Agency officials are to provide enough time for the establishment to hold the sampled lot.

According to FSIS' regulations, for calendar year 2007, the dollar limitation (for sales to hotels, restaurants, and similar institutions) for meat and meat food products is \$55,100 and for poultry products is \$44,400. While there are particular limitations (*quantity or product purchased*) of consumer purchases under the retail exemption, essentially, no dollar limitations exist (*particular limitations are outlined in 9 CFR 303.1(d)(2)(ii)*).

POINT OF SALE CONSUMER EDUCATIONAL MATERIALS

AAMP Meat Processing Inc. will also make consumer educational materials available at the retail store. The establishment firmly believes that everyone has an equal role in food safety. In general, this information will reiterate the need for proper consumer handling and cooking (160 °F) of ground beef products.

Out of an abundance of caution and to be proactive regarding potential *E. coli* O157:H7 contamination, AAMP Meat Processing Inc. will essentially have three new *E. coli* O157:H7 testing programs:

1. *E. coli* O157:H7 testing of carcass derived from cattle slaughtered at AAMP Meat Processing Inc. at least quarterly (at least once every 3rd month - 4 times annually).
2. *E. coli* O157:H7 testing of ground beef derived from cattle/carcasses slaughtered and fabricated at AAMP Meat Processing Inc. at least quarterly (at least once every 3rd month - 4 times annually).
3. *E. coli* O157:H7 testing of ground beef derived from beef components purchased from other USDA inspected establishments at least quarterly (at least once every 3rd month - 4 times annually).

AAMP Meat Processing Inc. has developed a tentative schedule that outlines the generic *E. coli* and *E. coli* O157:H7 testing program (Attachment #6). This schedule is only a reference document to outline the extensive testing program that will be implemented to address the potential *E. coli* O157:H7 contamination in ground beef products.

Owner, AAMP Meat Processing Inc.

HACCP Coordinator, AAMP Meat Processing Inc.

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