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DO YOU OWN/OPERATE A RAW BEEF PLANT?

HERE'S HOW TO REASSESS YOUR HACCP PLAN FOR E. COLI O157:H7

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If you either produce or process raw beef, the deadlines are rapidly approaching for you to reassess your HACCP plan for E. coli O157:H7. On October 7, 2002, USDA's Food Safety and Inspection Service issued a notice requiring all raw beef plants, including slaughterers, grinders, fabricators and further processors, to reassess their HACCP plans for the pathogen E. coli O157:H7, and take further action, including putting controls for E. coli in their plans if it is "a hazard reasonably likely to occur." If establishments do not believe that E. coli poses such a hazard in their operations they must show FSIS why they do not believe it is a hazard for them.

This notice also applies to state inspected plants in the 28 state inspection programs that are "equal to" federal inspection, as well as to USDA-inspected plants.

The FSIS notice was published because the Agency believes there is new information that shows E. coli O157:H7 to be more prevalent than previously thought. In fact, by issuing this notice, USDA assumes that establishments will find in their reassessment process that E. coli O157:H7 is a hazard reasonably likely to occur.

If you own or operate a small plant, you must complete your HACCP reassessment by February 4. If your plant is a very small one, the deadline for HACCP plan reassessment is April 7. (Large plants were required to reassess their plans by December 6.)

AAMP has met numerous times with USDA officials, posing questions on an ongoing basis to the Agency, and attempting to determine what beef plants must do to comply with the FSIS October 7 notice. Unfortunately, for the most part, FSIS has been closed-mouthed, not willing to say much about what beef plants must do in order to comply, other than to reassess their HACCP plans for E. coli O157:H7. The Agency claims that the E. coli notice is not a change in the regulation, although AAMP disagrees. We think the Agency is making new regulations, but disguising them as notices or directives so they don't have to allow comments from the meat processing industry and others about them. The answers from the Agency have been mostly sketchy, and FSIS has refused or been unable to answer many of the questions that have been posed by AAMP and other trade associations.

Since the notice was published on October 7, there have been many questions regarding verification of a slaughtering plant's interventions, as well as with what E. coli testing programs mean for lotting and

product trace back, particularly for trimmings. Many questions have not yet been answered, although FSIS says there will be additional information that will be helpful to processors when the Agency reissues a new version of **Directive 10,010.1**, the E. coli O157:H7 testing directive. But FSIS says it will not be reissued within the next few weeks. The Agency also can give no estimate of when the revised directive will be issued.

So while the following information is preliminary in nature, it should help our members and others to at least get started in complying with the FSIS notice. Recently, however, FSIS has started to answer some questions which we outlined for you here.

It is very important that you document your HACCP plan reassessment very carefully, including any changes you make in your HACCP plan. You should make a record on paper of the changes you make, how you arrived at those decisions, Why you made them, or why you decided against them.

If you decide to increase your testing for E. coli O157:H7, for example, you should explain why. FSIS has not indicated how many tests you would need to show that your HACCP plan is working. There is no indication from the Regulatory Agency how to "link" or "unlink" your products in the event of positive tests for E. coli O157:H7 or foodborne sicknesses that arise from the pathogen in product.

FSIS has said, though, that meat is most likely to become contaminated with the pathogen at the slaughterhouse; and therefore, processors and grinders might determine that the best control point in their HACCP plan would be a purchasing specification from their supplier rather than a control point in their own establishments. However, further processors will still need to address and prevent the growth of pathogens with temperature control in their HACCP plans.

Here's What Slaughterers Can Do

If you slaughter beef, whether you use it yourself, or act as a supplier, shipping it to other processing or grinding plants for them to use as raw materials, you must take "intervention steps" to do as much as you possibly can to insure that the materials do not contain E. coli O157:H7. You may already be taking steps on the kill floor or in your dressing procedures to eliminate this pathogen, but if you are not already doing so, you should now make it part of your HACCP plan.

The interventions you could use at slaughter include:

*Trimming to get rid of fecal material.

*A hot water rinse of at least 180 degrees F.

*A validated chemical anti-microbial treatment, such as an organic acid rinse.

Examples include acidified Sodium Chlorite and Peracetic Acid.

*A combination of the hot water and the organic acid rinse.

When applied properly, these technologies will reduce the risk that beef carcasses will be contaminated with E. coli O157:H7. You could enhance the effectiveness of what you do by combining some of these technologies. What may be new for some of you is that one or more of these interventions to remove E.

coli O157:H7 at the slaughter point should be part of your HACCP plan as Critical Control Points (CCPs) for beef slaughter. Possibly some low level of contamination could remain. Even at a very low level, growth of E. coli O157:H7, Salmonella and other pathogens could occur unless the carcasses are chilled properly. To make sure this happens, you should space your carcasses to allow for movement of the cold air between carcasses. Also you must have adequate chilling capacity. If carcasses touch each other during chilling, microbiological outgrowth could occur, possibly resulting in high levels of E. coli O157:H7 and Salmonella. Make spacing a Control Point.

You could also apply an additional anti-microbial treatment after chilling. Research shows that applying a validated chemical anti-microbial treatment after chilling will even further reduce contamination. In one study, a spray application of Acidified Sodium Chlorite on carcasses coming out of the cooler after slaughter resulted in a large reduction of E. coli and coliforms.

Another possible step is to make sure that the animals the producers bring you, or that you buy at auction houses, are clean. If not, the producers should be encouraged to wash them before they show up at the slaughterhouse door.

Steps For Processors and Grinders

Many AAMP members, especially beef grinders, will decide to implement purchase specifications as a result of their HACCP reassessments. These can be prerequisite programs, it does not have to be a new CCP for your HACCP plan. So in your hazard analysis at receiving, E. coli O157:H7 would not be "a hazard reasonably likely to occur." You justify this decision by using your prerequisite program that requires all beef products that you have bought to go through a validated intervention for E. coli O157:H7. You should obtain letters from your suppliers stating that the product you are buying from them has been through these interventions.

If you buy from a distributor, ask for a copy of similar letters, but ask your distributor to add this: That the distributor has made sure that the raw materials/product you are receiving from them has been kept at a proper storage temperature, so there has been no growth of pathogens, including E. coli O157:H7.

Do not write "prerequisite program" in your HACCP plan to justify it. Only write "purchasing specifications regarding E. coli O157:H7" or something similar, referring to the specification only.

With the purchase specifications in place, you must still carry out verification activities. These activities could include an occasional **Certificate of Analysis (COA)** that you would receive with products that are shipped to you, testing of product that is coming into your plant, finished product testing, and follow-up activities on what your supplier does, such as audits, deviations reports or surveys. It's up to you to choose what you want to do, but you should conduct some kind of verification activity on each supplier every so often. For example, you could do verification testing every month or every quarter. You don't have to verify each of your suppliers every time you do it, but your records must show verification activities for each supplier at some regular interval. USDA will accept Certificates of Analysis as a verification, but you must keep the records that verify it for you, such as the sampling procedure, how often sampling is done, and what the sample represents. products before they are permitted to enter into commerce.

FSIS continues to think that end-product sampling is an important verification tool, because in their view, that is the place where contamination would most easily be found.

FSIS says they will look favorably on beef plants that use several kinds of verification, including:

- *Incoming product testing.
- *Certificates of Analysis.
- *End product testing.
- *Audit or contact with suppliers to find out how the process is working in the slaughter plant.
- *If there is a positive test result, procedures on your supplier, FSIS would want you to carry out intensified verification, if you can identify who it is.

Working With Trimmings

If you produce your own trim to be used in grinding, you can choose to “re-lot” the trim by testing it before you grind it or before it is shipped as finished product in commerce. This would prevent you from necessarily having to implicate the whole muscle from which the trim came or other boxes that might be from the same incoming lot that are to be used at a later date.

Details of such a testing program should be written out and the individual sample you test should be a “representative sample” of the lot that you are testing. In the eyes of USDA, this would be “an additional layer of protection” and something for you to think about in lot exposure minimization if finished product testing produced a positive for E. coli O157:H7.

FSIS says it will take the most liberal view when linking product from a positive test result going back to whole muscle materials associated with the trim, or finished product that the “positive test” came from. If you are using an added step that prevents that “linkage”, you will then have less economic exposure. FSIS does not require or even suggest that trim be “relotted”, but this may be a benefit if you can do it.

If you do find a “positive” for E. coli O157:H7 in your trim, that does not automatically implicate any of the raw materials from the same lots coming into your plant that you have not yet processed. But you should take special steps with those lots, such as doing intensified testing of subsequent trim produced from those raw materials.

Other steps you could take in minimizing your lots could include:

- *Breaks in your cycles.
- *Being careful with rework or carry over.
- *Retrain plant personnel.
- *Defining your raw material lots and sampling plans.
- *Finished product testing.

Contamination can be reduced even further by decontaminating trimmings before grinding using FDA-approved processing help, such as Acidified Sodium or Citric Acid. This could result in an additional 1-2 log reduction in surface pathogens and further reduce contamination with E. coli O157:H7.

If You Use Blade Tenderization

If you blade tenderize your raw beef products, you should indicate to FSIS that E. coli O157:H7 "is not a hazard reasonably likely to occur." This is based on a study done by **Kansas State University** and the absence of illnesses caused by these products as reported by the **Centers for Disease Control and Prevention** alone. But according to FSIS, plants making this type of product do not have to implement a Critical Control Point for it. In order to show that E. coli O157:H7 is not a hazard reasonably likely to occur, you should write a prerequisite program for your supplier specifications, similar to specifications for ground products or processes that produce trim for grinding purposes.

You can also use Good Manufacturing Practices (GMPs) for blade tenderization as another means to protect yourself. These could include:

- *Trimming the outside of the product before blade-tenderizing.
- *Using a spray intervention on the product before you blade-tenderize.
- *Clean your equipment.
- *Reduce the number of times your product passes through the blade-tenderizer.

Dealing With Products From Overseas

Some AAMP members import product from Australia, New Zealand and other places for use as raw materials in grinding and other processing. In those two countries in particular, E. coli O157:H7 is not considered "a hazard reasonably likely to occur." FSIS tells us right now they are negotiating with Australia and New Zealand about those issues. There are reports that an agreement may be reached that those countries will be able to make that claim based on their own information and data. FSIS and the inspection agencies of Australia and New Zealand are trying to resolve the issue.

Non-Intact Products Not Ground Or Blade-Tenderized

What about a product that has been pumped using needles, such as corned beef? While all raw beef products must be included in your HACCP plan reassessment for the pathogen, FSIS has not indicated whether common cooking practices can be part of your decision-making whether the pathogen is "a hazard reasonably likely to occur." But it's a reasonable assumption that cooking practices, no Centers for Disease Control data about these products and supplier specifications will lead you to conclude that E. coli is not "a hazard reasonably likely to occur."

Refer To USDA-FSIS Guidance For Small/Very Small Plants

FSIS has sent small and very small plants a packet of guidance documents related to E. coli O157:H7, scientific articles about the prevalence of the pathogen in cattle coming to slaughter, and a copy of the Federal Register Notice requiring beef plants to reassess their HACCP plans for E. coli O157:H7. If you haven't received this, you can get one by contacting AAMP. Of particular importance in the packet is **Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim Products, and Guidance for Minimizing the Risk of E. coli O157:H7 and Salmonella in Beef Slaughter Operations**. If you have any questions about this information, please call or e-mail AAMP.

Two Purchase Specification Letters

(Use these two letters received by AAMP as examples of what you want from your supplier)

Statement From Excel:

"If ground beef is on this shipment, it has been subjected to an E. coli O157:H7 testing program. The samples tested negative for E. coli O157:H7. Please be advised that the testing confirms the absence of E. coli O157:H7 only in the specific sample tested, and not the entire product."

January 6, 2003

To Whom It May Concern:

Swift & Company is committed to food safety. We have uniform safety processes and procedures across our beef facilities, which are located in Grand Island and Omaha, Nebraska; Cactus, Texas; Greeley, Colorado; Hyrum, Utah; and Nampa, Idaho.

Swift's Food Safety Process consists of Standard Operating Procedures (SOPs), Sanitation Standard Operating Procedures (SSOPs), Hazard Analysis Critical Control Points (HACCP), and validated technology interventions, which are designed to eliminate or reduce E. coli O157:H7 below detectable levels. Our Food Safety Process is monitored by Operations personnel and verified by Quality Assurance and FSIS/USDA personnel in each plant. The FSIS/USDA personnel place the mark of inspection on the products before they are permitted to enter into commerce.

We require all animal suppliers to certify that they comply with existing FDA/USDA regulations regarding antibiotic and drug residues and ruminant-to-ruminant feed ban.

Our Food Safety Process utilizes technology interventions (Multiple Hurdle Strategy which include steam vacuums, pre-evisceration wash, thermal pasteurization (CCP), organic acid applications (CCP), and cold chain management (CCP) systems. The Institute for Environmental Health, located in Seattle, Washington, has independently tested and validated our intervention system.

We perform microbial testing on carcasses and trimmings destined for raw communitied finished products. While we employ exhaustive interventions and testing, there is no available technology which can guarantee that fresh meat products are "free of pathogens." In any situation where there may be a question about the quality of a particular product, it is handled according to FSIS/USDA guidelines and processed into fully cooked products or rendered inedible.

We use third party and customers' audits to confirm that our Food Safety Process is working. We also require our microbial laboratory service providers to submit to and pass a Laboratory Proficiency Program on an ongoing basis. We do not release microbial information to anyone other than our customers due to our policy of confidentiality.

Carriers of Swift & Company beef products are insured and bonded. Loads are sealed at the originating establishments and maintained under seal by the carrier in the event of a multi-stop load.

Our Food Safety Process includes a Recall/Market Withdrawal Procedure, which gives us trace-back and track-forward capabilities to ensure that the proper products and dates can be identified if necessary.

Our process also includes a product guarantee, which we provide to our customers upon request.

You are cordially invited to visit our facilities and review our processes (with proper notification) through your Sales Representative or other Swift & Company contact. We hope this information is useful to you and look forward to serving you as a customer and partner of Swift & Company.

Sincerely,

Warren Mirtsching
Vice President, Quality Assurance & Food Safety