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NEW MEASURES TO ADDRESS *E. COLI* O157:H7 CONTAMINATION

The U.S. Department of Agriculture's Food Safety and Inspection Service is adopting a series of new measures to further prevent *Escherichia coli* (*E. coli*) O157:H7 contamination in ground beef. The new measures are based on recent information indicating that *E. coli* O157:H7 is more prevalent than was previously thought. A Federal Register notice announcing these actions will be published.

BACKGROUND

In October 1994, FSIS declared *E. coli* O157:H7 to be an adulterant in raw ground beef and began a sampling program to test for it in federally inspected establishments and in retail stores. Raw ground beef was targeted because of its strong epidemiological link with *E. coli* O157:H7 infection, which can cause serious life-threatening human illnesses (hemorrhagic colitis and hemolytic uremic syndrome). Raw ground beef presents a significant public health risk because it is often cooked to an internal temperature that is insufficient to destroy pathogens. Thoroughly cooking ground beef products to an internal temperature of 160° F will destroy *E. coli* O157:H7 and result in a safe product.

In January 1999, FSIS published a statement clarifying that the public health risk posed by *E. coli* O157:H7 is not limited to raw ground beef products but includes intact raw beef products such as trimmings that are to be further processed into non-intact products. FSIS determined that if these types of intact beef products are positive for *E. coli* O157:H7, then they must be processed into ready-to-eat products or be deemed adulterated.

RISK ASSESSMENT FOR *E. COLI* O157:H7

In 1998, FSIS initiated a farm-to-table risk assessment to evaluate the public health impact of

E. coli O157:H7 in ground beef. The assessment includes evidence from a study presented by USDA's Agricultural Research Service (ARS) and illness estimates from the Centers for Disease Control and Prevention (CDC).

In February 2000, ARS presented evidence regarding the incidence of *E. coli* O157:H7 in animals entering the slaughter plant and at various stages in the slaughter process. ARS recorded that the proportion of animals presented for slaughter that were infected with *E. coli* O157:H7 was 28 percent, higher than previously reported. It was further found that an average of 43 percent of carcasses were contaminated with the pathogen.

In addition, CDC increased its estimates for illnesses associated with *E. coli* O157:H7. CDC now estimates that foodborne transmission of the pathogen annually causes more than 62,000 illnesses, 1,800 hospitalizations, and 52 deaths.

The *E. coli* O157:H7 draft risk assessment reflected this new data and concluded that *E. coli* O157:H7 is more prevalent than was previously thought. In response, FSIS has designed a series of measures to further prevent *E. coli* O157:H7 contamination.

To ensure transparency and a critical review of its scientific approach, FSIS submitted the draft risk assessment to the National Academy of Sciences (NAS) for scientific peer review. FSIS expects to receive the NAS peer review in fall 2002.

REASSESSMENT

The 1996 Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) final rule requires that federally inspected plants perform an analysis to identify food safety hazards that are

reasonably likely to occur in the production process and preventive measures to control those hazards. Establishments must develop a written HACCP plan to address and prevent all identified hazards for the process. Establishments are required to reassess HACCP plans at least annually and whenever information indicates a change in hazards reasonably likely to occur.

FSIS believes recent evidence regarding the prevalence of *E. coli* O157:H7 indicates that the pathogen is a hazard reasonably likely to occur at all stages of handling raw beef products. Therefore, FSIS is requiring all establishments that produce raw beef products to reassess their HACCP plans based on recent evidence.

Establishments must now determine whether *E. coli* O157:H7 is a hazard reasonably likely to occur by examining the adequacy of current controls, as well as whether their raw beef products tested positive for the pathogen in either FSIS or industry testing. If an establishment determines that *E. coli* O157:H7 is a hazard reasonably likely to occur, one or more critical control points designed to prevent contamination must be incorporated by the establishment or by their suppliers.

Rather than establishing a critical control point to address *E. coli* O157:H7 in their own production processes, grinding establishments may choose to maintain purchasing specifications requiring that their suppliers do so. However, FSIS recommends that grinders determine whether critical control points are also necessary in their own operations.

In addition, all establishments are required to conduct on-going verification activities to ensure that their critical control points are adequately addressing *E. coli* O157:H7 or that purchase specifications are preventing the pathogen from entering the facility. FSIS recommends that these verification activities include microbiological testing.

FSIS expects plants to perform this reassessment in phases according to plant size. Large, small and

very small plants (as defined in the preamble to the PR/HACCP final rule) must conduct their reassessment within 60, 120, and 180 days, respectively, of publication in the Federal Register.

FSIS intends to scrutinize the hazard analyses and HACCP plans of establishments that determine, after reassessment, that any preventive step for *E. coli* O157:H7 is unnecessary.

MICROBIOLOGICAL TESTING PROGRAM

FSIS is also amending segments of its microbiological testing program for *E. coli* O157:H7. Sections of an FSIS directive exempting some slaughter plants from FSIS' random *E. coli* O157:H7 testing will be eliminated. All ground beef plants will become part of the FSIS random verification testing program.

Also, FSIS is considering expanding its testing program to include trimmings and carcasses in addition to ground beef.

GUIDANCE TO INDUSTRY

FSIS has designed several guidance documents to help industry reduce the occurrence of *E. coli* O157:H7. *Guidance for Beef Grinders and Suppliers of Boneless Beef and Trim*, which was originally offered in 1998, has been expanded to include information for both grinders and their suppliers. In this publication, FSIS recommends that grinders keep product from different suppliers separate to prevent any potentially contaminated source from adulterating other source materials. Separation of these materials will also allow grinders to more easily identify the source of *E. coli* O157:H7 contamination, should the pathogen be detected.

Another publication has been developed to assist slaughter establishments as they reassess their HACCP plans. This guide includes examples of published studies on decontamination methods that can be used to establish critical control points to address *E. coli* O157:H7.

Finally, FSIS is providing guidance material on the

ingredients and sources of radiation used to reduce microorganisms on carcasses, ground beef, and beef trimmings.

For More Information

Media Inquiries: (202) 720-9113

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Consumer Inquiries: Call USDA's Meat and Poultry Hotline at 1-800-535-4555. In the Washington, DC, area, call (202) 720-3333. The TTY number is 1-800-256-7072.

Technical Inquiries: Dr. Dan Engeljohn (202) 720-5627