**UNITED STATES DEPARTMENT OF AGRICULTURE**
**FOOD SAFETY AND INSPECTION SERVICE**
**WASHINGTON, DC**

| # FSIS NOTICE | 05-09 | 1/7/09 |
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## MEASURES TO ADDRESS *E. coli* O157:H7 AT ESTABLISHMENT THAT RECEIVE, GRIND, OR OTHERWISE PROCESS RAW BEEF PRODUCTS

### I. PURPOSE

*E. coli* O157:H7 is hazard that establishments that receive, grind, or otherwise process raw beef products need to address in their hazard analysis. FSIS is issuing this notice because the rate at which it is finding *E. coli* O157:H7 in product, and the recent recalls because of the pathogen's presence, evidence that the measures employed by a number of establishments to address *E. coli* O157:H7 are inadequate.

*Key Points Covered*

- Provides Enforcement, Investigations and Analysis Officers (EIAO) with specific criteria that they are to consider when they assess whether these establishments have adequate support for how, based on their hazard analysis, they address *E. coli* O157:H7 in their HACCP systems.

- Provides Consumer Safety Inspectors (CSI) with instructions on how to conduct verification activities at establishments that use Critical Control Points (CCPs) to prevent, eliminate, or reduce *E. coli* O157:H7 in raw beef products or that use their Sanitation Standard Operating Procedures (Sanitation SOPs) or another prerequisite program to prevent occurrence of this pathogen.

### II. INADEQUATE MEASURES TO ADDRESS E. coli O157:H7

A. An establishment that receives, grinds, or otherwise processes raw beef products cannot conclude that *E. coli* O157:H7 is not reasonably likely to occur in its production process because the product it receives bears the mark of inspection. The mark of inspection is a reflection of a finding made by FSIS personnel that the establishment has followed the validated procedures in its HACCP plan, not that the pathogen has been eliminated or reduced to undetectable levels.

B. If inspection program personnel find that an establishment's only conclusion regarding control of the pathogen is a determination that *E. coli* is not reasonably likely to occur in its operation because the product that it receives bears the mark of inspection, they are to correlate with the District Office through the Front-line Supervisor to determine whether it is necessary for an EIAO to conduct a Food Safety Assessment, or whether an enforcement action such as a Notice of Intended Enforcement (NOIE) is warranted because the HACCP plan is inadequate (9 CFR 417.6(a)).

**III. MEASURES TO ADDRESS E. coli O157:H7**

A. There is no one, absolute way in which an establishment is to control or prevent *E. coli* O157:H7. Inspection program personnel may find in verifying the approach to the pathogen that the establishment is using CCPs in its HACCP plan, its Sanitation SOP or another prerequisite program, or a combination of these mechanisms, to do so.

B. An establishment receiving, grinding, or otherwise processing raw beef products may address *E. coli* O157:H7 by conducting finished product testing before pre-shipment review, having procedures for washing product when removed from Cryovac bags and trimming the outer surface of the product before producing non-intact product, using antimicrobials or other lethality treatments, or taking some other measures.

C. Establishments receiving, grinding, or otherwise processing raw beef products may use their Sanitation SOPs or other prerequisite programs to prevent *E. coli* O157:H7. The establishment in its hazard analysis is to have supporting and ongoing documentation that establishes that the pathogen hazard is not reasonably likely to occur in its operation because of the design and execution of its prerequisite program. Such prerequisite programs may include the use of purchase specifications.

D. If the establishment uses purchase specifications in a prerequisite program to support the effectiveness of the program, FSIS expects the establishment to have:

1. a document (e.g., letter of guarantee) from each supplier that provides assurance that the supplier employs CCPs that address *E. coli* O157:H7 and that describes those interventions;

2. certificates of analysis (COAs) (i.e., actual test results) and the sampling method used (e.g., N=60) by the supplier; and

3. records (e.g., the receiving establishment's own testing results, ongoing communication with suppliers, or third party audits) that demonstrate that the receiving establishment is executing its program to achieve the first two conditions in III. D. in a consistent and effective manner.

E. FSIS has identified three basic types of relationships in which a receiving establishment obtains the information in D. 1. and 2. above.

1. a direct relationship with its suppliers under which the receiving establishment is informed of the specific slaughter/dressing and fabrication controls employed by the supplier, including any trimming of external surface tissue and application of antimicrobial treatments demonstrated to meet specified microbial criteria established by the supplier and receiver (e.g., demonstrated by counts of microorganisms indicative of process control),

2. a more casual relationship with its suppliers under which the establishment receives documentation that provides information about the supplier's general slaughter/dressing and fabrication practices but does not assert that the products were processed to meet specified microbial criteria (e.g., counts of microorganisms indicative of process control),

3. an indirect relationship where the product received by an establishment is from brokers or importers (see F. below).

F. FSIS is aware that it may be difficult for an establishment receiving product from a broker or importer to meet all the criteria in D. 1. and 2. above. Therefore, if an establishment cannot meet these criteria, it may need to include the additional provisions in its food safety program, such as:

**NOTE**: There may be cases when the following applies to receiving establishments with direct or casual relationships with other official establishments.

1. If the establishment is unable to get an adequate letter of guarantee from a broker or importer, it should seek direct contact with the producing establishment of the product received by the broker or the importer to determine whether the suppliers have validated interventions and procedures.

2. If the establishment is unable to get a COA for each lot, it may obtain evidence from the broker or importer for each incoming shipment of raw beef materials that the materials were tested (e.g., N60), and that the test results were negative for *E. coli* O157:H7. The establishment may also have direct contact with the broker's or importer's suppliers to inquire about the sampling methods the supplier uses.

3. If the establishment is unable to meet to 1. and 2. above, the establishment should have put in place other mechanisms for controlling the presence of *E. coli* O157:H7, such as:

a. testing incoming product;

b. treating or washing the product when removed from Cryovac bags and trimming the outer surface before processing non-intact product;

c. testing finished product; or

d. using antimicrobials or other lethality treatments on raw beef product.

## IV. EIAO VERIFICATION ACTIVITIES

A. When conducting a food safety assessment (FSA) at an establishment that receives, grinds, or otherwise produces raw beef product, the EIAO is to follow the methodology in FSIS Directive 5100.1 to assess whether the establishment has properly supported the measures it takes to address *E. coli* O157:H7.

B. Because of the variety of ways an establishment can control or prevent this pathogen, the EIAO will need to evaluate how the establishment has validated its HACCP system. The EIAO is to assess, as set out in FSIS Directive 5100.1, Part IV III., *EIAOs Assessment of Validation*, whether the HACCP system includes some practical data or information reflecting an establishment's actual experience in implementing the HACCP plan. The EIAO is to determine whether the validation data demonstrate that the establishment can implement the HACCP plan and make it work to demonstrate that *E. coli* O157:H7 has been eliminated or reduced to a non-detectable level. An important element of validation is the identification or development of data that show that the establishment can apply the process or control to get the anticipated effect under actual in-plant operational conditions.

C. When reviewing any Sanitation SOP or prerequisite program that the establishment employs to prevent *E. coli* O157:H7 in raw beef products, the EIAO is to follow the methodology in FSIS Directive 5100.1, part III. I., *EIAO Assessment of the Sanitation SOPs,* or part IV II., *EIAOs Assessment of Prerequisite Programs*, to determine whether the hazard analysis has the supporting and ongoing documentation to demonstrate that the presence of the pathogen hazard is not likely to occur in the establishment.

D. In addition, the EIAO is to seek answers to the questions below to determine whether the establishment has the appropriate scientific support and decision-making documents associated with the development and use of its prerequisite program as required in 9 CFR 417.5(a)(1), and that the judgment made in its hazard analysis continues to be supported by the evidence from the system in operation.

### 1. Questions on the relationship the receiver has with its supplier

Does the receiver have a direct, casual, or indirect relationship with its supplier?

**NOTE**: If the relationship is direct or casual, EIAO are consider this first when seeking answer to questions 2 and 3, and if the relationship is indirect, EIAOs are to seek answers to question 5. The EIAO is to consider question 4 in either case.

### 2. Questions on the documents (e.g, letters of guarantee) from each supplier that describe the supplier's procedures.

a. Is there a description of the supplier's system, including a description of the validated CCPs the supplier uses to control the pathogen or other intervention or procedures (such as prerequisite programs) to address the pathogen?

b. Is there a description of the interventions and other procedures used by the supplier?

**3. Questions on certificates of Analysis (COAs) (i.e., actual test results) and a description of the sampling method used (e.g., N=60)**

a. Does the establishment require COAs for each lot of product?

b. Is the establishment receiving COAs and maintaining copies of the records?

c. Does the establishment have documentation from each supplier that identifies the laboratory method and sampling method and frequency it uses to support the COA, and if the method is different than the FSIS laboratory method and N=60, does the establishment have a record that explains why the laboratory and analysis method will produce results that it is the establishment can rely upon?

**4. Questions on maintaining written procedures and records (e.g., its own testing, ongoing communication with suppliers, or third party audits)**

a. Does the establishment maintain ongoing communication with its suppliers to ensure that what is described in the letter of guarantee and the test results or statements that accompany each shipment are accurate? If so, how frequent is such communication, and what is the receiving establishment's justification for the frequency? Is the communication documented and the documentation available to the EIAO?

b. Does the establishment contract with a third-party to conduct audits of its suppliers to ensure that what is described in the letter of guarantee, and the test results or COA, that accompany each shipment are accurate? If so, how frequent are the third party audits conducted, and what is the receiving establishment's justification for the frequency?

c. Does the grinding establishment test the incoming product? If so, is there documentation supporting the verification frequencies and the adequacy of the sampling and testing procedures? (See guidance document on *E. coli* O157:H7 testing at: http://www.fsis.usda.gov/PDF/Draft_Guidelines_Sampling_Beef_Trimmings_Ecoli.pdf

**5. Questions when the establishment receives raw beef product from brokers or importers?**

a. Does the establishment have a mechanism in place to contact the producing establishment of the product received by the broker or the importer to verify that the producing plant regularly takes one or more of the actions outlined in III. F. 2. to ensure the safety of the product? Does the receiving establishment document the communication and is the documentation available to the EIAO?

b. If the establishment is unable to get a COA for each lot, does it receive a general statement with each incoming shipment of raw beef materials that the materials

were tested, and that the test results were negative for *E. coli* O157:H7? Does the establishment maintain direct contact with the broker's or importer's suppliers to inquire about the sampling methods the supplier uses?

c. If the answer is no to a. or b. above, does the establishment have CCPs in its HACCP plan or other procedures (e.g., prerequisite programs) to address *E. coli* O157:H7 in raw beef products? For example:

i. does the establishment have procedures to test the incoming product? If so, is there documentation supporting the verification frequencies and the adequacy of the sampling and testing procedures?

ii. does the establishment have procedures where it washes the parts after removing them from Cryovac bags and trims the outer surface before producing non-intact product?

iii. does the establishment have procedures for finished product testing before pre-shipment review? If so, is there documentation supporting the verification frequencies and the adequacy of the sampling and testing procedures? or

iv. does the establishment use antimicrobials or other lethality treatments on raw beef product.

D. EIAOs are to consider all the factors above when writing their FSAs at establishments that produce raw beef as set out in FSIS Directive 5100.1. Negative answers to the questions above do not automatically mean that the establishment's system is inadequate. Also, in cases where establishments have some of the criteria discussed in this notice in their prerequisite programs but not all elements, EIAOs are to take into consideration the establishment's use of validated CCPs to control *E. coli* O157:H7.

## V. CSI VERIFICATION ACTIVITIES

A. If a CSI finds that an establishment that receives, grinds, or otherwise processes raw beef products has a CCP to control *E. coli* O157:H7, he or she is to verify that, as set out in FSIS Directive 5000.1, Chapter II, paragraph III, the establishment has validated that the CCP achieves the anticipated effect. If the CSI has questions regarding how the establishment validated the CCP, he or she is to contact the DO. The DO is to determine whether it is necessary to send an EIAO to the establishment.

B. If a CSI finds that an establishment that receives, grinds, or otherwise processes raw beef products addresses the prevention of *E. coli* O157:H7 in raw beef products through a prerequisite program, he or she is to verify that, as set out in FSIS Directive 5000.1, Chapter II, paragraph IV, the establishment's prerequisite program is being executed as designed. If the CSI has questions regarding how the establishment has designed or is executing prerequisite programs, he or she is to contact the DO. The DO will determine whether it is necessary to send an EIAO to the establishment.

Refer questions regarding this notice to the Policy Development Division through askFSIS at http://askfsis.custhelp.com or by telephone at 1-800-233-3935.

Assistant Administrator
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