Questions and Answers on FSIS Directives 10,010.1, Revision 1, 5000.2, and 6420.2

Part I. Questions and answers on Directive 10,010.1, Revision 1 (on the FSIS web page at: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10.010.1.pdf)

A. The sampled lot and questions on FSIS' sampling:

1. Question: What is an example of a supportable basis that establishments may use to define lots or sub-lots of raw ground beef product that they produce?

Answer: Establishments may be able to lot or sub-lot raw ground beef product based on establishment testing. To justify a lot or sub-lot definition based on testing, the establishment must have statistical confidence of detecting contamination events. In addition to testing, there may also be other means by which establishments define lots or sub-lots of raw ground beef product that they produce. Establishments are responsible for supporting their bases for defining the sampled lot.

2. Question: Can "clean-up to clean-up" be used as a method of distinguishing one portion of production of raw ground beef from another portion of production?

Response: No. The establishment should support its basis for distinguishing one portion of production from another, and clean-up to clean-up is not an adequate basis for distinguishing one portion of production from another. If an establishment finds product positive or presumptive positive (and does not confirm it negative) for *E. coli* O157:H7, it is important that the establishment conduct complete cleaning and sanitizing procedures to prevent possible *E. coli* O157:H7 cross contamination in product produced after the positive or presumptive positive finding. In this situation, the establishment would need to have a basis other than the clean-up to determine that the ground product produced after the clean-up from the same source materials as the product found positive or presumptive positive is not implicated by the test results.

3. Question: An establishment produces coarse ground chubs from trimmings that test negative for *E. coli* O157:H7. A grinding establishment uses these chubs as its only source material for the production of ground beef patties. It takes several days for the grinding establishment to use a shipment of these chubs. The grinding establishment fully implements its Sanitation SOP procedures after each day's operation. If the grinding establishment starts using a shipment of these chubs on Monday, and FSIS takes a sample on Tuesday, how much product should the grinding establishment hold?

Response: If the grinding establishment does not have documentation to support that any portion of the coarse ground chubs used in the production of ground

beef patties is distinguishable from other chubs in the same shipment, the grinding establishment should hold all ground beef products produced from that shipment of chubs pending availability of FSIS' test results. The type of documentation the grinding establishment uses to support a distinction among the chubs in the shipment could include records from the supplier documenting that the supplier segregated the trimmings into sub-lots, randomly selected samples from the sub-lots, and tested the samples for *E. coli* O157:H7. Similarly, the grinding establishment may have documentation showing that the supplier or the grinder segregated the coarse ground chubs into sub-lots, randomly selected samples from the sub-lots, and tested the samples for *E. coli* O157:H7. If the supplier's testing provides the basis for sub-lotting the product, the supplier should provide information to the grinder concerning the supplier's sampling and testing methodology. To justify a distinction among the chubs in the shipment, the supplier's or the grinder's *E. coli* O157:H7 sampling and testing procedures should achieve statistical confidence of detecting *E. coli* O157:H7 contamination events. Based on this type of testing, each sub-lot could be managed as independent of other sub-lots of coarse ground chubs.

4. Question: In the scenario in the preceding question #3, how much advance notice should FSIS provide the establishment prior to collecting a raw ground beef product sample for *E. coli* O157:H7 testing?

Response: The directive instructs inspection program personnel to notify the official establishment that they will be collecting a sample of raw ground beef product and to provide enough time for the establishment to hold the sampled lot (see Part II, B., 3. of the directive). In the scenario in the preceding question #3, if the grinding establishment does not have documentation to support that any of the chubs are distinguishable from others, FSIS should notify the grinding establishment prior to the establishment's use of any of the chubs from a particular shipment.

If the grinding establishment has data to show that some of the chubs are distinguishable from others, FSIS should notify the grinding establishment prior to the establishment's using one of the distinguishable portions of the source materials.

Inspection program personnel need to be familiar enough with the process to realize that, in some cases, notifying the establishment one day prior to collecting the sample may not be adequate time to allow the establishment to hold all product represented by the sample. If the establishment requests more than a couple days' notice prior to FSIS' collection of the sample, inspection program personnel will consider the request based on establishment product and process flow.

5. Question: Are establishments provided one day's notice before FSIS collects a sample for *E. coli* O157:H7 testing?

Response: Inspection program personnel would provide one day's notice if such advance notice is sufficient for the establishment to hold the sampled lot (see Part II, B., 3. of the directive and Q&A #9 in attachment 1 to the directive). In some cases, FSIS may provide more than one day's notice (see preceding question and answer). If less than one day's advance notice would not cause a hardship for the establishment, FSIS may provide less than one day's notice before FSIS collects a sample for *E. coli* O157:H7 testing.

6. Question: An establishment uses 3 intact source materials. The source materials are mixed to manufacture raw ground beef products. Can FSIS select a sample from one of the intact source materials and then pull a sample of the selected product after it is ground?

Response: No. Under these circumstances, FSIS will collect its sample from the finished ground product that is a mixture of the source materials. If FSIS selected a sample from one of the source materials and then pulled a sample from the ground source material that has not been mixed with other source materials, the sample would not represent the production process or the product normally produced. As explained in the question, the source materials are mixed together to produce raw ground beef products.

7. Question: After an FSIS positive *E. coli* O157:H7 test result, the establishment takes corrective action according to 9 CFR 417.3. How much time does the establishment have before FSIS takes another verification sample?

Response: If FSIS finds a raw ground beef product sample positive for *E. coli* O157:H7, FSIS generally collects at least one follow-up verification sample. If inspection program personnel identify no significant problems through the HACCP 02 procedure (see Part IV, A., 3., b. of the directive), inspection program personnel take a follow-up sample as soon after the establishment has taken its corrective action as possible (see Part V, A., 1. of the directive).

B. Products subject to FSIS sampling for *E. coli* O157:H7 under this directive:

1. Question: Is ground buffalo meat subject to FSIS verification sampling and testing for *E. coli* O157:H7?

Response: No. Ground buffalo is not a raw ground beef product.

2. Question: If an establishment receives raw ground beef product produced by another official establishment and only regrinds the product, is the reground product subject to FSIS verification testing for *E. coli* O157:H7.

Response: Yes, such product is subject to FSIS verification testing for *E. coli* O157:H7. As FSIS explained in Q&A #3 in attachment 1 to the directive, FSIS intends to develop a risk-based verification testing program for *E. coli* O157:H7. Once FSIS implements risk-based verification testing for *E. coli* O157:H7, FSIS expects to begin sampling establishments that only regrind product at a lower frequency. For information on product that is inspected and passed at an official establishment and then found positive for *E. coli* O157:H7 at another establishment, see Part I, D., 1. of this Q&A document.

3. Question: If establishments do not grind product but only form patties, are they subject to FSIS verification testing for *E. coli* O157:H7?

Response: Yes. As explained in Q&A #3 in attachment 1 to the directive, once FSIS implements risk-based verification testing for *E. coli* O157:H7, FSIS expects to sample product from patty formers less frequently than product from establishments that grind product. Just as FSIS intends to sample establishments that only regrind product at a lower frequency, FSIS expects to sample patty formers at a lower frequency.

4. Question: In the future, does FSIS have plans to sample cheek meat and weasand meat for *E. coli* O157:H7?

Response: Cheek meat and weasand meat may be raw ground beef components and raw beef patty components. Currently, FSIS may sample and test raw ground beef components and raw beef patty components (including cheek meat and weasand meat) for *E. coli* O157:H7 at supplying establishments when FSIS finds a raw ground beef product sample at a grinder or retailer positive for *E. coli* O157:H7. Similarly, if FSIS finds a raw ground beef product at an official establishment positive for *E. coli* O157:H7, and the same establishment produced the source materials for the ground product, FSIS may test the components at this establishment.

As FSIS stated in Q&A #1, in attachment 1 to the directive, FSIS intends to develop a random sampling and testing program for raw ground beef components and raw beef patty components. Therefore, FSIS may randomly sample and test cheek meat and weasand meat for *E. coli* O157:H7 when the Agency implements a random sampling and testing program for raw ground beef components and raw beef patty components.

5. Question: Does FSIS have plans to sample and test fabricated, formed, or comminuted raw beef products for *E. coli* O157:H7 (e.g., products defined in 9 CFR 319.15(d))?

Response: FSIS does not currently sample these products. However, such raw products are non-intact beef products that would be adulterated if contaminated with *E. coli* O157:H7. In Q&A #1 in attachment 1 to the directive, FSIS explained

that it intends to sample non-intact products other than ground beef in the future. Therefore, fabricated, formed or comminuted raw beef products may be subject to FSIS' future sampling and testing for *E. coli* O157:H7.

6. Question: If raw ground beef product is identified for in-plant purposes to indicate that it is for cooking only, will FSIS sample and test the product for *E. coli* O157:H7?

Response: No, FSIS would not sample such product, provided the establishment's hazard analysis and flow chart show that this product will be cooked by the establishment and identify establishment controls that ensure that this product does not enter commerce until after it has been cooked. FSIS will revise instructions to inspection program personnel to clarify this issue.

7. Question: If an establishment grinds raw beef product but sends it to other establishments that fully cook the product, does FSIS sample and test the product for *E. coli* O157:H7?

Response: No, FSIS normally does not sample such product if it is clearly intended to be fully cooked. FSIS' policy of not sampling and testing this product is consistent with FSIS' policy of not sampling and testing for *Listeria monocytogenes* in ready-to-eat product that is labeled "for further processing" and that is expected to receive a lethality treatment at another inspected establishment (see FSIS Directive 10,210.1, Amendment 6). FSIS will revise instructions to inspection program personnel to make clear that raw ground beef product that is labeled "for further processing" and that is appropriately controlled to ensure that the product receives a validated lethality treatment adequate to destroy *E. coli* O157:H7 at another inspected establishment should not be sampled for *E. coli* O157:H7 testing.

C. Notifying FSIS of positive results:

1. Question: If an establishment receives raw ground beef product or raw ground beef components from another establishment, and establishment testing shows that those components are positive or presumptive positive (and not confirmed negative) for *E. coli* O157:H7, is the establishment that received the components required to notify FSIS inspection program personnel of these test results?

Response: If the establishment does not accept the product because it is adulterated, the establishment is required to notify the inspector in charge of the kind, quantity, source, and present location of the product and of the respects in which the product is adulterated (see 9 CFR 320.7). If the establishment receives and accepts product that is positive or presumptive positive (and not confirmed negative) for *E. coli* O157:H7, FSIS recommends that the establishment inform FSIS that it has received such product. However, notifying

FSIS is not required. The HACCP regulations (9 CFR 417.5) require that establishments document the receipt of positive or presumptive positive product. FSIS will verify that an establishment receiving positive or presumptive product maintains control of the product and has addressed *E. coli* O157:H7 in its hazard analysis and HACCP plan, so that the product will receive an adequate lethality treatment to destroy the pathogen (see Part VIII of the directive). As noted in the following Q&As #3 and #4, FSIS will also verify that the establishment that produced the positive or presumptive positive product maintains records showing that the product received appropriate disposition.

2. Question: Do inspection program personnel have to be present to verify proper disposition of raw beef product that is positive or presumptive positive (and not confirmed negative) for *E. coli* O157:H7?

Response: No. If FSIS inspection program personnel are not present when disposition of such product occurs, they will verify that such product received proper disposition through records review.

3. Question: If a product tests positive or presumptive positive (and is not confirmed negative) for *E. coli* O157:H7, will FSIS verify that every lot implicated by the sample that the establishment intends to send to another official establishment for further processing is actually sent to the designated establishment and actually receives appropriate disposition?

Response: When performing HACCP 02 procedures, FSIS will verify that the establishment that produced the *E. coli* O157:H7 positive or presumptive positive product maintains records showing that every lot implicated by the test results received appropriate disposition at an official establishment, landfill operation, or renderer. Records of receipt at an official establishment, landfill operation, or renderer are not adequate to show that the product received appropriate disposition. Rather, the establishment that produced the positive or presumptive positive product must obtain records evidencing that the specific product was appropriately further processed or destroyed.

4. Question: Does the establishment have to notify FSIS when it transports to a further processing plant product that tested positive or presumptive positive (and was not confirmed negative) for *E. coli* O157:H7?

Response: FSIS recommends that the establishment inform FSIS when moving such product. However, notifying FSIS is not required. If FSIS finds the product positive for *E. coli* O157:H7, FSIS will be aware if product disposition is to occur off site (see Part IV, A., 5. of the directive). If the establishment found the product positive or presumptive positive (and did not confirm it negative) for *E. coli* O157:H7, when FSIS performs HACCP 02 procedures, the Agency will verify that the establishment 1) maintains records identifying the official establishment, renderer, or landfill operation that received the product; 2) maintains control of

the product while it is in transit; 3) maintains records showing that the product received proper disposition; and 4) completes pre-shipment review for that product only after it has received records showing that the product received proper disposition from the establishment, renderer, or landfill operation where disposition occurred (see Part VII, B., 2. of the directive).

D. Implications of positive test results and control of positive product:

1. Question: An establishment finds raw ground beef or raw beef product intended for use in raw ground beef product positive or presumptive positive (and does not confirm the product negative) for *E. coli* O157:H7. The establishment labels the product with an instructional statement (e.g., "for cooking only") and sends the product to a cooking establishment for further processing to destroy the pathogen. In this situation, is the establishment that produced the positive or presumptive positive product required to obtain records from the cooking establishment documenting that the product received proper disposition?

Answer: Yes. Raw ground beef, other non-intact raw beef product, and intact beef product intended to be used for raw ground beef or other non-intact raw beef product that is positive or presumptive positive (and not confirmed negative) for *E. coli* O157:H7 is adulterated unless it is further processed to destroy the pathogen. Establishment records and HACCP documents (e.g., the flow chart and hazard analysis) for intact product, such as beef manufacturing trimmings, should indicate whether the product is intended for use in raw, non-intact beef product.

If an establishment produces raw beef product that is adulterated because it is *E. coli* O157:H7 positive or presumptive positive and sends that product to another official establishment, landfill operation, or renderer, the establishment that produced the product must obtain and keep records documenting that the product received proper disposition from the official establishment, landfill operation, or renderer where disposition occurred. Documentation that the product went to an inspected facility that ordinarily cooks the product, and records of receipt from such a facility, are not sufficient documentation that the product actually received proper disposition. Rather, the establishment that produced the positive or presumptive positive product must obtain records evidencing that the product was appropriately processed.

The HACCP regulations require that establishments maintain records evidencing proper disposal of beef product that is adulterated because the product is *E. coli* O157:H7 positive or presumptive positive (and not confirmed negative). Specifically, 9 CFR 417.3 requires that establishments that produce such product take corrective actions, and 9 CFR 417.5(a)(3) requires that they maintain records documenting their corrective actions. Sections 417.3(a)(4) and (b)(3) require that establishments' corrective actions ensure that no product that is injurious to health or otherwise adulterated enters commerce. As part of

preshipment review, 9 CFR 417.5(c) requires establishments to review the records associated with the production of adulterated product to ensure corrective actions were taken, including proper disposition of product.

2. Question: If FSIS finds an establishment's product positive for *E. coli* O157:H7, does FSIS request that the supplier of any source materials used in the product recall the source materials?

Response: In this situation, the inspector in charge at the supplying establishment ensures that inspection program personnel perform a HACCP 02 procedure to verify that the supplier met the applicable regulatory requirements at all CCPs in the HACCP plan for the production lots sent to the establishment or retail facility where FSIS found the positive. In addition, FSIS may test the raw ground beef components and raw beef patty components at the supplying establishment (see Part VI, A. and B. of the directive). If FSIS finds product positive for *E. coli* O157:H7 at the supplier, inspection program personnel, the District Office, and Recall Management Staff work together to determine the necessity of product retention, detention, or recall (see Part IV, A. of the directive). FSIS generally will not request that a supplying establishment recall product unless FSIS finds the supplier's product positive for *E. coli* O157:H7 or unless, through the HACCP 02 procedure, FSIS identifies other conditions that justify a recall.

3. Question: An establishment finds non-intact raw beef product or intact raw beef product to be used in non-intact raw beef positive in a screening test for *E. coli* O157:H7, does not confirm the result, but does conduct a second screening test for *E. coli* O157:H7 on the product and finds it negative. Must such product be further processed at an official establishment or sent to a renderer or landfill operation?

Response: Yes. Negative screening test results do not supercede the presumptive positive results. A screening test is not a conclusive (specific) test for the pathogen.

4. Question: Is an establishment required to identify itself as one that accepts *E. coli* O157:H7 positive or presumptive positive product?

Response: No, the establishment is not required to identify itself as such. However, the HACCP regulations (9 CFR 417.5) require that the establishment document the receipt of presumptive positive or positive product. If the establishment intended to accept presumptive positive or positive product on an on-going basis, the establishment could document receipt of such product in its decisionmaking documents, rather than document receipt of each lot of such product. In addition, the establishment must address *E. coli* O157:H7 in its hazard analysis and HACCP plan, so that the product will receive an adequate lethality treatment to destroy the pathogen (see Part VIII of the directive).

5. Question: If an establishment tests a beef carcass and finds it positive or presumptive positive (and does not confirm it negative) for *E. coli* O157:H7, how must the establishment process the carcass?

Response: The carcass is an intact product. Therefore, it is not necessarily adulterated if found positive for *E. coli* O157:H7. However, if any part of that carcass is intended for use in non-intact raw beef product, it would be adulterated. Therefore, the establishment should ensure that all of the carcass is used to produce products that will be processed to fully destroy the pathogen (e.g., by cooking or irradiation) or is used to produce products that will reach consumers in an intact state. The establishment's records should show that the product from the *E. coli* O157:H7 positive carcass is processed appropriately.

6. Question: When raw beef product is positive or presumptive positive (and not confirmed negative) for *E. coli* O157, is the record of lethality treatment sufficient to show that the product received proper disposition, or should the establishment conduct post lethality testing for *E. coli* O157:H7 on the product?

Response: FSIS does not require *E. coli* O157:H7 product testing after the product has been subjected to a lethality treatment adequate to destroy the pathogen. Records, as part of a validated HACCP plan, showing that the product underwent a full lethality treatment for *E. coli* O157:H7, such as cooking, would be sufficient.

7. Question: An establishment trims whole intact rounds. The rounds are not needle tenderized. After trimming and slicing, the round steaks are vacuum packed and boxed. The trim is used in the production of ground beef. FSIS collects a sample from the ground beef made from the trim of whole intact rounds. FSIS finds the ground beef positive for *E. coli* O157:H7. How does this affect the whole intact rounds?

Response: If the establishment has clearly defined in its HACCP documentation that the vacuum packed round steaks will reach the consumer in their intact state, the whole rounds would not be considered adulterated. Intact raw beef product that reaches consumers in an intact state is not adulterated if contaminated with *E. coli* O157:H7. Intact steaks with *E. coli* O157:H7 surface contamination are customarily cooked in a manner that ensures that these products are not contaminated with *E. coli* O157:H7 when consumed.

8. Question: Once a renderer owns raw beef product that is positive or presumptive positive (and not confirmed negative) for *E. coli* O157:H7, the establishment no longer has control of this product. What kinds of records of disposition must the establishment obtain from the renderer?

Response: The establishment should obtain a record from the renderer that shows that the product received proper disposition. The record could include information necessary to identify the product, the number of pounds of raw beef product received, and the number of pounds of such product rendered.

9. Question: Is it acceptable to send product that is positive or presumptive positive (and not confirmed negative) for *E. coli* O157:H7 to an inspected or non-inspected cold storage facility before sending it to a further processing establishment?

Response: Generally, positive or presumptive positive product may not be shipped through a cold storage facility because the establishment that produced the product must maintain control of it during shipment. Ownership is typically passed once the cold storage facility holds the product. However, there may be circumstances in which an establishment can ship positive or presumptive positive product through a cold storage facility. Specifically, the establishment that produced the product would have to do the following:

1) maintain control of the product while it is in transit (e.g., through company seals) or ensure such product moves under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1);

2) maintain records identifying the cold storage facility and how the products will be controlled while stored in the cold storage facility;

3) maintain records identifying the official establishment, renderer, or landfill that received the product; and

4) maintain records that show that the product received proper disposition, including documentation evidencing proper disposal of the product from the official establishment where disposition occurred or from the renderer or landfill where disposition occurred (see Part VII, B., 2. of the directive).

Questions #10 and #11: In the following questions #10 and #11, official establishment #1 produces raw beef product that is positive or presumptive positive (and not confirmed negative) for *E. coli* O157:H7. Establishment #1 moves the product to official establishment #2 (an official establishment, not a warehouse). Establishment #2 freezes and stores the product until it is shipped to official establishment #3. Establishment #3 has a lethality step as a critical control point (CCP) validated to reduce *E. coli* O157:H7 to below detectable levels. Official establishment #2 is re-boxing and re-labeling the product as a service to official establishment #1. In this situation, official establishment #2 never owns the product. However, the bills of lading change hands between official establishments #1 and #3.

10. Question: Can establishment #2 in the scenario above receive *E. coli* O157:H7 positive or presumptive positive product and re-box, re-label, and store it frozen until it is shipped to official establishment #3? Under these circumstances, establishment #1 would continue to own the product while establishment #2 re-boxes, re-labels, and stores the product.

Response: FSIS would not prevent establishment #2 from receiving product that is positive or presumptive positive for *E. coli* O157:H7. However, necessary controls and documentation in this scenario would be critical. Establishments #1 and #3 would be required to maintain records showing that they controlled the product, and that the product received appropriate disposition (see Parts IV, A., 2., 5; VII, B., 2; and VIII of the directive). Although establishment #2 never owns the product, establishment #2 would need to keep records on behalf of establishment #1 to show that establishment #2 kept the product separate from other products throughout every step of repackaging.

11. Question: Some positive or presumptive positive product that has been re-packaged by the second establishment is shipped to a third establishment that applies full lethality to the product. What is the responsibility of the second establishment, if, after lethality, the third establishment ships some of the positive or presumptive product before the second establishment receives records from the third establishment documenting that the product has received lethality?

Response: The second establishment never owns the product and cannot control what happens to the product once it is received by the third establishment that is applying lethality. The third establishment owns the product. If the third establishment has identified *E. coli* O157:H7 as a food safety hazard and has implemented validated CCPs to destroy the pathogen, the third establishment could ship the product. The first establishment that produced the positive or presumptive positive product is required to maintain records showing that this product received proper disposition and could not conduct pre-shipment review until it has received documentation evidencing that the product has received proper disposition. As explained above, the second establishment is only performing a service for the first establishment. Therefore, the second establishment is not required to keep records showing that the product received proper disposition.

12. Question: If an establishment without a lethality step in its process receives raw beef product that is positive or presumptive positive or for *E. coli* O157:H7 (as in the circumstances described in the preceding Q&A #9), how long can the product be stored before it is required to go to an establishment where lethality is applied?

Response: FSIS does not have requirements for the amount of time such product can be stored before lethality. If disposition of the product is to be delayed, inspection program personnel are to work with their front-line

supervisors to determine how to work with the establishment to ensure proper and timely disposal of the product (see Part IV, A., 4. of the directive).

E. FSIS' test results and general questions on *E. coli* O157:H7 testing:

1. Question: Can establishments request to have FSIS' *E. coli* O157:H7 test results e-mailed to them?

Response: Yes. If an establishment is interested in receiving FSIS' *E. coli* O157:H7 test results (and test results for ready-to-eat products) electronically, it should notify the inspector in charge and provide its e-mail address to the inspector in charge. The inspector in charge will then enter the establishment's e-mail address in the performance based inspection system (PBIS) version 5.1. PBIS allows only one e-mail address per establishment.

2. Question: How many days after FSIS sampling will FSIS' *E. coli* O157:H7 test results become available?

Response: Typically, FSIS' *E. coli* O157:H7 confirmation test results become available three to four days after FSIS collects the sample.

3. Question: Is there a test to determine whether *E. coli* O157:H7 contamination came from the raw product or the environment?

Response: No, such a test is not available.

F. Questions on imported product:

1. Question: If an importer receives fresh or frozen raw beef product with a health certificate indicating that the product is not at risk of being positive for *E. coli* O157:H7, is that product subject to FSIS sampling and testing for *E. coli* O157:H7? Should the importer test the product for *E. coli* O157:H7?

Response: Imported raw ground beef product would be subject to FSIS port-of-entry sampling and testing for *E. coli* O157:H7, regardless of the claims made on the foreign health certificate. An official U.S. establishment that receives the product should assess for itself whether it is necessary to conduct *E. coli* O157:H7 verification testing of imported raw beef product that is accompanied by a foreign health certificate indicating that the product is not at risk of being positive for *E. coli* O157:H7.

2. Question: Does FSIS test for *E. coli* O157:H7 in imported raw beef product from a "skipped" lot?

Response: A "skipped" lot is a group of similarly processed or packaged products from a foreign country that is not assigned a specific "type-of-

inspection" by the Automated Import Information System (AIIS) at port-of-entry reinspection. FSIS will override a "skipped" lot assignment and test such product at port-of-entry if needed. When a foreign establishment is implicated in a positive finding at an official U.S. establishment, such product could be sampled in supplier trace back sampling. These sample requests would be scheduled through the AIIS.

G. Establishments' verification sampling and testing:

1. Question: How does an establishment determine the necessary frequency of its verification testing for *E. coli* O157:H7?

Response: Establishments are responsible for determining the necessary frequency of their verification testing for *E. coli* O157:H7. The regulations require that establishments maintain documents supporting the monitoring and verification procedures the establishment has selected and the frequency of those procedures (9 CFR 417.5(a)(2)). Therefore, establishments are required to maintain documents supporting the adequacy of their verification testing program for *E. coli* O157:H7. In determining the necessary frequency of establishment verification testing for *E. coli* O157:H7, establishments should consider such factors as: the establishment's history of *E. coli* O157:H7 positive test results or unconfirmed presumptive positive test results; the number of verification tests for *E. coli* O157:H7 that the establishment's suppliers conduct relative to the volume of product the suppliers produce; the volume of raw beef product the establishment produces; the establishment's and its suppliers' level of confidence of finding the pathogen in product, if it is present; whether additional testing is necessary during the *E. coli* O157:H7 high prevalence season; and the effectiveness of interventions for *E. coli* O157:H7 that the establishment and its suppliers use.

Please see Part I, A., 1. of this document for information on establishments' lotting or sub-lotting raw ground beef product based on establishment testing.

2. Question: Should establishments consider the frequency of and results of FSIS' *E. coli* O157:H7 verification sampling and testing in determining the necessary frequency of establishment verification sampling and testing?

Response: No. Establishments should support through their decisionmaking documents their decisions. FSIS' regulatory sampling should not be a consideration. Establishments cannot predict when or how frequently FSIS will sample and test their products.

3. Question: Can establishments test for process control indicators to verify that their controls for *E. coli* O157:H7 are functioning effectively?

Response: At present, there are no adequate indicators or surrogate organisms for *E. coli* O157:H7. Establishments may be able to demonstrate that they are reducing bacterial contamination effectively through verification testing of process control, e.g., through aerobic plate count. However, to verify that specific controls for *E. coli* O157:H7 are functioning effectively, establishments should conduct verification testing for *E. coli* O157:H7.

4. Question: An establishment has thousands of negative test results for *E. coli* O157:H7. At what point can an establishment conclude that *E. coli* O157:H7 is not reasonably likely to occur based on these negative test results?

Response: FSIS cautions that it would be unwise for an establishment to conclude that the pathogen is not reasonably likely to occur based on numerous negative test results for the pathogen. FSIS has previously advised that establishments should strongly consider the possibility that *E. coli* O157:H7 is a hazard reasonably likely to occur in their production of beef products, especially if an establishment produces non-intact product that has been or could be adulterated with *E. coli* O157:H7 or produces intact product that is to be used for non-intact product, and this non-intact product has been or could be found to be adulterated with *E. coli* O157:H7 (67 FR 62329).

H. Instructional and disclaimer statements

1. Question: If inspection program personnel find noncompliances involving instructional and disclaimer statements, what trend indicator should they use on the Noncompliance Report (NR)?

Response: Q&A #19, in attachment 1 to the directive, indicates that inspection program personnel are usually to cite 9 CFR 417.5 and to use the recordkeeping trend indicator when documenting in an NR most of the possible noncompliances involving instructional and disclaimer statements.

2. Question: Are cooking instructions on product produced and packaged for the National School Lunch Program considered “instructional statements” as discussed in the directive?

Response: No. These products are labeled to go to institutional customers, not official establishments. Products bearing instructional statements addressing *E. coli* O157:H7 must go to official establishments only.

3. Question: If an establishment includes instructional statements or disclaimer statements for in-plant purposes on product that does not leave the establishment, is the establishment’s use of these statements required to meet the criteria in the directive? Will FSIS conduct the verification activities in the directive that address establishments’ use of these statements?

Response: No. If the establishment's use of such statements is for internal purposes only, FSIS inspection program personnel will not assess whether the establishment is appropriately using such statements, as they would with respect to product going to other official establishments. Establishments should not submit in-plant labels to FSIS for approval.

Questions #4-6: In the following questions #4-#6, official establishment #1 ships product bearing a disclaimer statement ("product has not been tested for *E. coli* O157:H7") to official establishment #2 (an official establishment, not a warehouse). Official establishment #2 only re-packages and re-labels the product with its establishment number. Official establishment #2 has a temperature control CCP to control the outgrowth of *E. coli* O157:H7. Official establishment #2 freezes and stores the product until it is shipped to official establishment #3. Official establishment #3 has a lethality step as a CCP validated to reduce *E. coli* O157:H7 to below detectable levels. Official establishment #2 is re-boxing and re-labeling the product as a service to official establishment #1. However, the bills of lading change hands among official establishments #1, #2, and #3.

4. Question: How would FSIS expect the second establishment to address *E. coli* O157:H7 in its HACCP plan?

Response: Because the establishment is receiving product with a disclaimer statement, the establishment must address the receipt of this product in its HACCP plan as if it may be contaminated with *E. coli* O157:H7. In the scenario above, establishment #2's controls include a temperature control CCP and controls to ensure that the product goes to establishment #3, where the product will undergo a lethality step as a CCP validated to reduce *E. coli* O157:H7 to below detectable levels. These controls are acceptable in this situation.

As explained in the directive, when the Labeling and Consumer Protection Staff (LCPS) approves the use of disclaimer labeling statements, such statements can only be used on products destined for official establishments that address *E. coli* O157:H7 in their HACCP plans (see Part IX, B.). Normally, the establishment that receives raw beef product with a disclaimer statement must address *E. coli* O157:H7 in its HACCP plan and may not send the product to another establishment for further processing. In the scenario above, establishment #2 is performing a service for establishment #1. Therefore, FSIS is allowing establishment #2 to address *E. coli* O157:H7 by maintaining the controls described in the previous paragraph and by sending the product to establishment #3.

5. Question: What records must be maintained by the second establishment regarding the product with the disclaimer statement?

Response: The establishment should maintain control of this product and should keep records documenting the control of the product and that the critical limits are met while the product is in this establishment. This establishment also needs to have documentation to reflect that the product is destined to go only to an official establishment that has a lethality step, validated to reduce *E. coli* O157:H7 below detectable levels, as a CCP in its HACCP plan.

6. Question: Does the third official establishment report the lethality disposition to the second (boxing) official establishment, who then reports to the first official establishment? Or does the third establishment report directly to the first? Is there any benefit in reporting through the second establishment?

Response: It is important for all establishments to keep accurate records of the product that is produced under their HACCP plans. In this scenario, the important point is that records should be present at all three establishments to document that the product that was produced in the first establishment is the same product that received lethality in the third plant. Since the product was re-packaged and re-labeled in the second plant, it may be difficult to provide this documentation without involving documentation from the second establishment. All three establishments must keep records required under 9 CFR 320.1, including bills of sale, invoices, bills of lading, and receiving and shipping papers for the beef products involved. Because transactions did not involve any positive or presumptive positive product, the first and second establishments are not required to obtain and keep records of disposition from the third establishment.

I. Supplier records and supplier certification letters:

1. Question: Some grinders do not purchase source materials directly from suppliers. Rather, they purchase source materials handled by one or more distributors. Are the distributors required to maintain records concerning the suppliers?

Response: Yes, each distributor is required to maintain records of purchase. The regulations require that any person that engages in the business of buying, selling, or transporting in commerce, or storing in or for commerce, or importing, any livestock carcasses, or parts or products of livestock carcasses, to keep records of each transaction involving their purchasing or receiving of these products (9 CFR 320.1(b)(1)). These records must show the name or description of the livestock product purchased or received (9 CFR 320.1(b)(1)(i)) and the name and address of the seller of the livestock product purchased (9 CFR 320.1(b)(1)(iv)).

2. Question: A grinding establishment has purchase specifications addressing *E. coli* O157:H7. The grinder receives a certification letter from each of its suppliers indicating that the raw beef products that the suppliers provide have been treated with interventions addressing *E. coli* O157:H7 that meet the grinders' purchase

specifications. Are these certification letters adequate documentation to show that the incoming product meets the grinder's purchase specifications?

Response: No. This type of certification letter does not supply enough information to document that the supplier is meeting the grinder's purchase specifications. The grinder should have additional means of ensuring that the supplier is meeting the grinder's purchase specifications, such as verification testing or auditing of the supplier. FSIS would likely send an Enforcement Investigations and Analysis Officer (EIAO) to a grinder who relies on such certification letters, conducts no verification testing, and has no other means of ensuring that the incoming product meets its purchase specifications. The EIAO would conduct a comprehensive food safety assessment.

In addition, FSIS intends to implement a process that will allow the Agency to conduct appropriate verification activities at suppliers when the test results of establishments that receive the supplier's product indicate that the product may be *E. coli* O157:H7 positive.

J. Questions from retailers:

1. Question: Is FSIS going to produce any training materials or example materials of what the Agency expects concerning ground beef recordkeeping at retail?

Response: In the October 7, 2002, Federal Register, FSIS explained that, under 9 CFR 320.1(b)(1), Federally inspected establishments and retail facilities are required to keep records of each transaction involving their purchasing or receiving any meat or meat food product. These records must show the name or description of the articles they purchase or receive (9 CFR 320.1(b)(1)(i)) and the name and address of the seller of the articles they purchase (9 CFR 320.1(b)(1)(iv)). Federally inspected establishments and retail facilities must provide FSIS access to these records (9 CFR 320.4, 21 U.S.C. 642).

As is stated in the October 7, 2002, Federal Register, at the time FSIS collects samples of ground beef from retail facilities, FSIS will obtain from the retail facility the names and establishment numbers of the establishments supplying the source materials for the lot of ground beef sampled, the supplier lot numbers and production dates, and any other information that would be useful to suppliers if they are later notified of an *E. coli* O157:H7 positive finding.

Finally, in the October 7, 2002, Federal Register, FSIS also stated that the Agency expects that supplier lot numbers and production dates are normally available at Federal grinding establishments and retail facilities. In addition, FSIS stated that it expects that retail facilities would normally obtain the contact information that FSIS is collecting when it collects samples of ground beef from retail facilities (67 FR 62332).

Therefore, retail facilities should consistently maintain adequate records concerning suppliers of source material for ground beef products, as required by regulations and the Federal Meat Inspection Act.

FSIS has developed compliance guidelines for industry, entitled, "Compliance Guidelines for Establishments on the FSIS Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7." The compliance guidelines include some guidance on grinding records at plants that retailers may find useful. The compliance guidelines are on the FSIS web page at: http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010_1/ecolio157h7dirguid4-13-04.pdf).

2. Question: If a retailer cuts up a bottom round flat for roasts and, in the trimming process, produces trimming intended for grinding, does the retailer have to record supplier information for the bottom round flat? Can the retailer mix these trimmings with other shop trimmings and create a "batch" ground beef log?

Response: Retailers can create trimmings and use the trimmings to produce ground beef. However, because intact products are not adulterated if contaminated with *E. coli* O157:H7, this product may not have undergone any interventions (such as antimicrobial treatment) for *E. coli* O157:H7 at the supplier. Therefore, this product may be at a higher risk of being contaminated with *E. coli* O157:H7 after grinding than product that was ground at an official establishment. Beef product intended for use in raw ground beef products often undergoes interventions for *E. coli* O157:H7 at an official establishment. In addition, if whole muscle cuts at retail are held at elevated temperatures for a period of time, the levels of any *E. coli* O157:H7 present in the product could have increased.

FSIS personnel do not collect samples of raw ground beef product that is received and sold as case-ready product or raw ground beef product that is only re-packaged at the retail store. FSIS personnel also do not collect raw ground beef product that is ground at retail if the retail facility only regrinds product previously ground at official establishments and does not conduct any practices that would introduce *E. coli* O157:H7 in the product (see Part X, A. of the directive). On the other hand, if retailers grind whole muscle beef cuts or trim, the ground product would be subject to FSIS sampling and testing for *E. coli* O157:H7.

If FSIS collects a sample of ground product produced from trimmings at retail, the directive instructs FSIS program investigators to obtain and record the names and establishment numbers of the establishments that produced the product from which the store-generated trim was derived (see Part X, A., 5. of the directive). A retail association informed FSIS that when FSIS samples raw ground beef product at retail and collects information on suppliers, retail facilities typically

provide information for all the suppliers that they used for the day, rather than provide the specific suppliers for the sample collected. In the Q&A document at http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010_1/Ecoli_QA.pdf, FSIS has stated that this practice is acceptable (see part IX, #6). FSIS recommends that retail facilities track the specific suppliers used for the raw ground beef products they produce. Such tracking could limit the amount of product subject to recall in the event that FSIS finds product positive for *E. coli* O157:H7, and the product the sample represented has been made available for retail sale. However, FSIS understands that retail facilities combine trim from multiple suppliers throughout a day's production and that tracking the specific suppliers for each raw ground beef product produced throughout the day may not be practicable.

3. Question: If a retail store puts out a T-bone steak with 3 days' shelf life, and by day 2 the steak has lost its "sales appeal," can the retailer grind this rewrap into ground beef? If the retailer can do this, how would the facility log it? The T-bone steak would have lost its box identity when it was cut, priced, labeled and put into the display case.

Response: FSIS regulations allow retailers to grind whole muscle cuts. However, as is noted in the preceding Q&A #2, whole muscle cuts may be at a higher risk of being contaminated with *E. coli* O157:H7 after grinding than product that was ground at an official establishment.

As is also noted in the preceding Q&A #2, if retailers grind whole muscle beef cuts, the ground product would be subject to FSIS sampling and testing for *E. coli* O157:H7. When they collect the sample, FSIS program investigators obtain from the retail facility the names and establishment numbers of the establishments supplying the source materials for the lot of raw ground beef product sampled (see Part X, A., 5. of the directive). If FSIS finds the product positive for *E. coli* O157:H7, and the product the sample represented has been made available for retail sale, FSIS will request that the retail facility recall the product. In order to limit the amount of product subject to recall, FSIS recommends that retailers come up with a system to track the suppliers of the source materials of all ground product.

4. Question: If a retailer chooses to purchase subprimals instead of case ready, fine or coarse ground beef, who is liable if FSIS finds this raw ground beef product positive for *E. coli* O157:H7?

Response: If FSIS finds a raw ground beef product sample collected from a retail facility positive for *E. coli* O157:H7, and the product the sample represented has been made available for retail sale, FSIS will request that the retail facility recall the product. The directive instructs FSIS personnel to collect from the retail facility the names and establishment numbers of the establishments supplying the source materials for the lot of raw ground beef product sampled.

Source materials could include trimmings from meat packers, store generated trim, or whole muscle cuts (including subprimals). Therefore, in the event of an FSIS positive finding in raw ground beef product produced at retail, FSIS uses the information it collected at retail on suppliers to go to the suppliers. Inspection program personnel perform a HACCP 02 procedure at the suppliers to verify that the suppliers met all regulatory requirements in producing the product that tested positive after grinding. Also, FSIS may test source materials at the supplying establishments for *E. coli* O157:H7. (See Parts VI and X of the directive.) FSIS will not generally request that the supplying establishment recall product unless FSIS finds the supplier's product positive for *E. coli* O157:H7 or unless, through the HACCP 02 procedure, FSIS identifies other conditions that justify a recall.

5. Question: Is it mandatory that retailers keep an up-to-date wash, rinse, and sanitizing log at the grinder?

Response: FSIS does not require sanitizing logs at retail grinders. However, sanitizing logs at retail grinders would be useful to show that the sanitation program is well documented and monitored.

FSIS personnel would not collect raw ground beef product that is ground at retail if the retail facility only regrinds product previously ground at official establishments and does not conduct any practices that would introduce *E. coli* O157:H7 in the product. An example of a situation in which FSIS personnel would collect samples from retail would be if the retail store grinds case-ready coarse ground product in a grinder also used to grind store trim and the sanitation program is not well documented, monitored, and verified for effectiveness (see Part X, A., 4.).

6. Question: Is there a mandatory or suggested number of times the grinder is to be washed, rinsed and sanitized daily?

Response: No. However, FSIS recommends that retail facilities maintain a sanitation program that is well documented and monitored.

Part II -- FSIS Directive 5000.2 (on the FSIS web page at: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5000.2.pdf)

1. Question: What is the period of time establishments must maintain records that are available to FSIS for review?

Response: The period of time establishments must keep records depends on the type of record in question. If records in question support the hazard analysis, they must be maintained on-site for as long as they support that analysis. If the records document monitoring of CCPs and their critical limits or verification procedures or results, establishments are required to keep these records for at least one or two years, depending on the product being produced. The records

described in the preceding sentence must be maintained on-site for six months and may be maintained off-site after that period of time. Records documenting the establishment's Sanitation SOPs must be maintained for at least six months and can be maintained off-site after 48 hours following completion. Business records to which FSIS has access (described in 9 CFR 320.1 and 381.175) must be maintained for two years after December 31 of the year in which the transaction to which they relate occurred (and for longer periods if the Administrator of FSIS requires their retention for purposes of any investigation or litigation under the Federal Meat Inspection Act or Poultry Products Inspection Act).

2. Question: How will FSIS evaluate the microbial, chemical, or Adenosine tri phosphate (ATP) procedures and results when there is not a standard (industry or in house) set for the specified test?

Response: FSIS Directive 5000.2 instructs inspection program personnel to review the results of any testing and of any monitoring activities that the establishment has performed that may have an impact on the establishment's hazard analysis. Even if there are no industry standards for a particular test, if the test results are related to decisions in the food safety system, these results must be available to FSIS personnel for review.

As explained in Part I, G., 1. of this document, the regulations require that establishments support the monitoring and verification procedures they have selected and the frequency of those procedures. Therefore, in the absence of industry standards for a certain test, if the test is a monitoring or verification procedure, the establishment would be expected to have in-house standards for assessing the test results. When reviewing establishments' monitoring and verification test results, in the absence of industry standards, FSIS would verify that establishments respond appropriately to their test results based on the establishments' standards.

Part III -- FSIS Directive 6420.2 (on the FSIS web page at: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/6420.2.pdf)

1. Question: Are intestines and stomachs subject to the zero tolerance requirements?

Response: No. The only meat products identified in the directive that are subject to the zero tolerance requirements at this time are carcasses, head meat, cheek meat, and weasand meat.

2. Question: At what point does FSIS verify zero tolerance for head meat, cheek meat, and weasand meat?

Response: Directive 6420.2 explains, “Inspection program personnel are to select product at the end of the harvesting process, after all of the establishment controls and interventions. This verification may occur at the time of packaging or when the product is placed in a container for storage” (Part III, B., 2.).

3. Question: Are there pictures to go along with the directive?

Response: All existing training materials for identifying fecal material are still applicable. A few pictures on fecal and ingesta identification may be found in training material for the original zero tolerance training (Cattle Clean Meat Program).

4. Question: At what point does FSIS verify zero tolerance for livestock carcasses?

Response: The directive describes where inspection program personnel are to perform their verification checks. The rail inspection station is the last point prior to harvesting the carcass before the mark of inspection may be applied. Zero tolerance in livestock carcasses is verified, documented, and enforced at or immediately after the final rail.

5. Question: Does the directive cover enforcement for bile contamination?

Response: Zero tolerance is for fecal, ingesta (in livestock), and milk (in livestock) contamination. The directive does not include enforcement actions involving bile contamination. However, 9 CFR 310.18(a) states, “Carcasses, organs, and other parts shall be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter; however, if contamination occurs, it shall be promptly removed in a manner satisfactory to the inspector.” Although findings of bile contamination on carcasses may be noncompliances, they are not zero tolerance noncompliances.