FSIS Compliance Guideline for Controlling Meat and Poultry Products Pending FSIS Test Results

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What is the purpose of this Compliance Guideline?

The purpose of this guidance document is to help domestic establishments and importers of record comply with the Food Safety and Inspection Service's (FSIS) new policy that product FSIS tests for adulterants will not be allowed to move into commerce until acceptable results become available. Specifically, it articulates:

- Which products and FSIS sampling and testing programs are subject to this policy;
- How domestic establishments can meet FSIS's requirement for meat and poultry establishments to hold or control product when FSIS collects a sample;
- How an establishment determines the amount of product it needs to hold;
- How importers of record can meet FSIS's requirement to hold or control product when FSIS collects a sample; and
- How an importer of record determines the amount of product they need to hold.

It is important to note that this Guideline represents FSIS's current thinking on this topic and should be considered usable as of its issuance. Guidelines will be continually updated to reflect the most current information available to FSIS and its stakeholders.

Who is this Compliance Guideline designed for?

This guidance is designed for all FSIS regulated meat and poultry establishments and importers of record whose products are subject to:

- FSIS verification testing for pathogens or chemical residues considered adulterants in FSIS regulated products, and
- FSIS verification of non-food safety consumer protection regulatory requirements (e.g., protein-fat-free and moisture in hams).

Therefore, this guidance applies to most products subject to FSIS verification testing with the exception of raw products subject to routine FSIS verification testing for *Salmonella* or other pathogens (such as *Campylobacter*) and poultry carcasses or other raw poultry parts subject to routine FSIS verification testing for residues. The applicable domestic and import testing programs are outlined further in this document.

How can I comment on this Compliance Guideline?

FSIS is seeking comments on this guidance document as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the document will be updated in response to the comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal Online submission at regulations.gov: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to http://www.regulations.gov and follow the online instructions at that site for submitting comments.

Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700. All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: FSIS Compliance Guideline for Meeting Test & Hold Requirements. Comments received will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

Why is this policy being implemented?

FSIS has asked, but had not required, official establishments and importers of record to maintain control of products tested for adulterants while waiting for receipt of all test results. FSIS has found, however, inconsistencies with those controls. Consequently, recalls have occurred because product was already in commerce by the time unacceptable test results came back from the laboratory. Therefore, FSIS announced that it is changing its procedures, and that products subject to this policy will not be able to enter commerce until receipt of all test results that bear on the determination as to whether those products are adulterated are received. For more information see the Federal Register Notice (77 FR 73401), announcing the final policy available at http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0044FN.pdf.

Guidance for domestic establishments on controlling meat and poultry products pending FSIS test results

What domestic products are subject to this policy?

Under the new policy, the following products tested by FSIS under domestic sampling and testing programs cannot move into commerce until acceptable results become available:

- Raw, non-intact beef or veal products such as ground beef, hamburgers, and patties and raw products that are components of non-intact products, including beef manufacturing trimmings, bench trim, heart meat, head meat, cheek meat, weasand meat, product from Advanced Meat Recovery (AMR) systems, low temperature rendered lean finely textured beef (LFTB), partially defatted beef fatty tissue, and partially defatted chopped beef, tested for *E. coli* O157:H7 and non-O157 Shiga-toxin producing *Escherichia coli* (non-O157 STEC);
- Ready-to-eat (RTE) products tested for *Listeria monocytogenes* and *Salmonella;*

- RTE product that passed over food contact surfaces that have been tested by FSIS for the presence of *Listeria monocytogenes* or *Salmonella*;
- Livestock carcasses tested for residue by FSIS of drugs, such as antibiotics, sulfonamides, or avermectins, or the feed additive carbadox under domestic sampling and testing programs; and
- Products that are tested for non-food safety consumer protection verification (e.g., protein-fat-free and moisture in hams).

The policy does not cover:

- Raw meat or poultry products that FSIS has tested for *Salmonella* or other pathogens (such as *Campylobacter*) that FSIS has not designated as adulterants in those products and
- Poultry carcasses subject to FSIS testing for drug residues. Because of the significant number of poultry carcasses in a lot, because of the economic effect of holding such a lot, and because, historically, FSIS has not seen residue problems in poultry tested for residues, such product would not need to be held from commerce pending acceptable test results (76 FR 19955).

Can an establishment move product off-site pending final test results?

Yes, an establishment is not required to hold product tested by FSIS for adulterants at the establishment, provided it has effective controls in place for it to move elsewhere under its ownership so that the product does not enter into commerce until the establishment receives acceptable results.

> **NOTE:** FSIS inspectors do not retain products tested by FSIS for adulterants pending test results; however, when FSIS inspection program personnel believe an animal may contain violative levels of residues, they will continue to deem it ``U.S. Suspect,'' retain the carcass, and submit samples for residue testing.

What does FSIS consider adequate controls when product is moved from the establishment prior to receipt of laboratory results?

Establishments are to maintain the integrity of the lot and use any effective mechanism to control the product. Adequate controls may include company seals. The Agency will require establishments to document and support that they can control the product pending the availability of test results. FSIS personnel will verify this documentation at the time of sample collection. If the movement of product results in a change of ownership, then the product is considered to have entered commerce.

When will FSIS consider domestic product to be in commerce?

FSIS recognizes that the mark of inspection is pre-printed on the package label of many products, and that it is most efficient to allow the product to be packaged and labeled with the printed mark of inspection as part of the production process. FSIS will continue to allow meat and poultry establishments to package and label products sampled and tested for adulterants with the mark of inspection. However, such product will not be eligible for shipment into commerce until acceptable test results for adulterants are available.

KEY QUESTION

Question: Can an establishment package and label products with the mark of inspection before acceptable test results for adulterants are available?

Answer: Yes, FSIS recognizes that the mark of inspection is pre-printed on the package label of many products, and that it is most efficient to allow the product to be packaged and labeled with the printed mark of inspection as part of the production process. FSIS will continue to allow meat and poultry establishments to package and label products sampled and tested for adulterants with the mark of inspection. However, such product will not be eligible for shipment into commerce until acceptable test results for adulterants are available.

In addition, to move product off-site pending FSIS test results, establishments cannot complete pre-shipment review or transfer ownership of the product to another entity. When a meat or poultry establishment completes a pre-shipment review (9 CFR 417.5(c)), the establishment indicates that it takes full and final responsibility for applying its Hazard Analysis and Critical Control Point (HACCP) controls to the product that it has produced. Pre-shipment review can be accomplished if the product is at a location other than the producing establishment, as long as the review of appropriate documents and compliance with 9 CFR 417.5(c) occurs before the product leaves the control of the producing establishment. If the establishment has completed pre-shipment review pending test results, and the results are positive, the establishment has produced and shipped adulterated product into commerce.

What is the minimum amount of time product will have to be on hold or under control for pending FSIS test results?

The following table summarizes the minimum number of days from receipt to when the result is received, depending on whether the result is determined to be acceptable or unacceptable by analysis type.

Analysis	Minimum Number of Days from Receipt When the Result Is:	
	Acceptable	***Unacceptable***
E. coli O157:H7 and non-O157 in raw beef products	2	4
Listeria monocytogenes in RTE products	3	6
Salmonella in RTE products	1	5
Residue (antibiotics, sulfonamides, or avermectins or the feed additive carbadox) in livestock	4*	Will depend on what is screened and the number and type of additional analyses required
Non-food safety consumer protection verification	Will depend on the type of analysis	Will depend on the type of analysis

**Does not include the time (12 – 24 hours minimum) it takes to freeze the sample prior to shipping to the laboratory.*

FSIS begins testing of all raw beef and RTE products for microbiological pathogen analysis, and all residue testing, the day of receipt, including Saturdays. Non-food safety consumer protection verification analyses are started Monday through Friday on the day of receipt; analysis of non-food safety samples received on Saturdays are started on Mondays. In regard to sample discards, any sample that the FSIS laboratory may discard would occur the day of receipt and would not increase turnaround times in any way. Official establishments can receive lab sample results from the Agency electronically.

More information on the various FSIS laboratory methodologies including time-frames for receipt of results can be found in the Microbiological Lab Guidebook and the FSIS Analytical Chemistry Laboratory Guidebook available at: http://www.fsis.usda.gov/Science/Guidebooks_&_Methods/index.asp.

How can an establishment determine the amount of product it needs to hold?

The establishment is responsible for having a supportable basis to define the sampled lot. The sampled lot is the product represented by the sample tested for by FSIS. In order to limit the amount of product affected by a sample result, the establishment may be able to limit the size of the sampled lot on the day FSIS collects a sample. For sampling purposes, lots should be defined so that if a positive result is found on one lot, the product from the other lot would not be implicated. Two such lots are called (mutually) independent or microbiologically-independent lots. Guidance on how to

define sampled lots by product and analysis type is provided below.

Guidance for Determining Lot Sizes

Guidance for determining lot sizes when FSIS collects a sample is provided for each domestic sampling and testing program below. This guidance can be used by establishments to limit the amount of product on hold when FSIS collects a sample.

Determining the Sampled Lot for Raw Beef Products Subject to E. coli O157:H7 and non-O157 Testing

A production lot of ***raw beef products*** can be defined in many ways. FSIS does not recognize "clean-up to clean-up" alone as a supportable basis for distinguishing one portion of production of raw beef product from another portion of production. This is because shiga-toxin producing *Escherichia coli* (*E. coli*) (STEC) organisms such as *E. coli* O157:H7, *E. coli* O26, O45, O103, O111, O121 and O145 are generally not environmental contaminants and, therefore, would not be completely addressed through cleaning and sanitizing. Guidance for lotting different types of raw beef products is described.

Raw beef products that are components of non-intact products

FSIS samples and tests the following raw beef products that are components of non-intact products for *E. coli* O157:H7 and in some cases, non-O157 STEC: beef manufacturing trimmings, bench trim, heart meat, head meat, cheek meat, weasand meat, product from AMR systems, low temperature rendered lean finely textured beef (LFTB), partially defatted beef fatty tissue, and partially defatted chopped beef.

Considerations that may be used to determine the sampled lot (alone or in combination) for these types of raw beef products include:

- Any scientific, statistically based sampling programs for shiga-toxin producing *Escherichia coli* (STEC) organisms, particularly *E. coli* O157:H7, non-STEC, or their associated virulence markers (e.g., *eae* and *stx* genes) that the establishment uses to distinguish between segments of production;
- Sanitation Standard Operating Procedures (Sanitation SOPs) or any other prerequisite programs used to control the spread of STEC cross-contamination between raw beef components during production. The following may lead to the cross-contamination between raw beef components during production:
    - improper sanitary dressing;
    - insanitary product contact surfaces on equipment such as machinery and employee hand tools;
    - improper employee hygiene;

- Processing interventions that have been validated to limit or control STEC contamination;
- Beef manufacturing trimmings and raw beef components or rework carried over from one production period to another (carrying rework over from one production period to another compromises microbiological independence between lots); and
- Use of same source materials during different production periods (if the components are being generated at an establishment that is not a slaughter establishment), provided product from one supplier could not have cross-contaminated the product from the other.

The following are examples of ways the official establishment can limit its lot size:

An establishment could produce bench trim from primals that are then mechanically tenderized and cut into steaks. In order to limit the sampled lot to the bench trim, the establishment could trim the primals, apply a validated intervention to the primals, and then tenderize the primals and cut them into steaks. In the event that FSIS collects a sample of bench trim that is found to be positive, the establishment could support that the non-intact steaks were microbiologically independent using the processing intervention validated to control STEC contamination, provided the critical operational parameters of the intervention were implemented properly.

Another example of how an establishment could lot beef manufacturing trimmings would be by using a robust sampling and testing program in which the establishment samples every combo bin (or other unit of product up to 10,000 pounds) using the N60 sampling plan and tests each sample for *E. coli* O157:H7 or their associated virulence markers (e.g., *eae* and *stx* genes). In this case, each combo bin of beef manufacturing trimmings would be considered a lot. If FSIS were to collect a sample from one combo bin of product, and the sample was found to be positive for *E. coli* O157:H7 or a non-O157 STEC , the establishment could support the release of the other lots of product using the results of their own robust testing program. Such robust testing would also be a way for establishments to support microbiological independence of finished product produced from the same production lot of source materials from a single supplier that were found positive for *E. coli* O157:H7.

For other raw, intact beef products that are components of non-intact products produced at slaughter establishments such as head meat, heart meat, and cheek meat, establishments often will lot product by slaughter day because of the use of common product contact surfaces that are not cleaned and sanitized until the end of the production day. In large establishments, components such as head meat, heart meat, and cheek meat are usually transported on a moving viscera table and in small establishments a viscera truck is often used. If these product contact surfaces are not cleaned between use, all product that came in contact with that equipment since the last clean-up is considered part of the same lot due to the opportunity for cross-contamination. Cleaning and sanitizing of product contact surfaces may be used as a factor in defining lot size in this case because the components were produced from one

or more carcasses slaughtered and dressed consecutively or intermittently within a defined period of time (e.g., production day). Therefore, any contamination should be limited within that defined period of time.

In limited cases, a single **carcass** may be considered a stand-alone lot. This may occur in the limited cases when FSIS collects follow-up samples directly from the **carcass** in response to an FSIS positive sample. For example, FSIS will collect follow-up samples directly from the carcass at an originating slaughter establishment if that establishment sent carcasses to a receiving establishment that produced bench trim from those carcasses that was then used in ground beef which FSIS tested and found positive. Product from different carcasses can be considered as independent lots provided the meat from the carcasses from each lot was handled so as to not cross-contaminate one another. This includes having assurances that the carcasses were not co-mingled. In those cases only the sampled carcass would be held. If the establishment does not prevent carcasses from being commingled or does not have adequate controls to prevent cross contamination among carcasses, it will not be able to designate one carcass as a stand-alone lot for sampling.

Raw non-intact beef products

FSIS samples and tests raw non-intact beef products that meet the standard of identity for ground and chopped beef (9 CFR 319.15(a)), hamburgers (9 CFR 319.15(b)), and beef patties (9 CFR 319.15(c)) for *E. coli* O157:H7.

The same considerations listed on pages 6-7 for determining the sampled lot of raw beef products that are components of non-intact products may be used to determine the sampled lot of raw non-intact beef products that FSIS samples and tests.

> **NOTE:** Additional guidance on sanitation practices beef grinders can implement to prevent the introduction of bacterial hazards into their process can be found on page 1 of the Sanitation Guidance for Beef grinders (available at http://www.fsis.usda.gov/PDF/Sanitation_Guidance_Beef_Grinders.pdf).

The following are examples of ways establishments can limit its lot size of raw ground beef products:

An establishment may define lots by source materials. STEC organisms tend to contaminate source materials during the slaughter and dressing process and so any contamination in source materials would likely be supplier specific. This lotting practice would be acceptable if the product from one supplier does not cross-contaminate the product from the other. For instance, following the grinding of product from one supplier, the lines and equipment were sanitized before the product from the next supplier was processed. It is important to note that if multiple lots of raw ground beef product were produced from source materials from the same production lot of a single supplier, and some of this product was found positive for E. coli O157:H7, a scientific basis is necessary to justify why any raw ground product produced at the grinder from

those source materials should not be considered adulterated (67 FR 62333).

Another example of how an establishment could lot ground beef would be by using a robust sampling and testing plan in which ground beef samples are collected in 65 gram grab portions every 30 minutes of processing and combined into 1 composite sample (five 65 gram samples would be combined into a 325 grams composite) to be tested for *E. coli* O157:H7 or their associated virulence markers (e.g., *eae* and *stx* genes). Using this plan, an establishment could lot product in 2.5 hour production segments and support microbiological independence for those segments.

The recommendations and information discussed above regarding defining the sampled lot can also be found in the:

- Guidance for Small and Very Small Establishments on Sampling Beef Products for E. coli O157:H7 found at: http://www.fsis.usda.gov/PDF/Draft_Guidance_SVSP_sampling_for_ecoli.pdf;
- Compliance Guideline for Sampling Beef Trimmings for *E. coli* O157:H7 found at: http://www.fsis.usda.gov/PDF/Draft_Guidelines_Sampling_Beef_Trimmings_Ecoli.pdf; and the
- Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers found at: http://www.fsis.usda.gov/PDF/Compliance_Guide_Est_Sampling_STEC_0512.pdf.

KEY QUESTION

Question: If an establishment produces two lots of ground beef from the same source materials and FSIS test results from one lot of product come back as unacceptable (e.g., positive for *E. coli* O157:H7), will the second lot of product need to be recalled if it was released into commerce?

Answer: It depends. The Recall Committee evaluates all production factors and control measures and then determines the scope of the affected product subject to recall. If multiple lots of raw ground beef product were produced from source materials from the same production lot of a single supplier, and some of this product was found positive for *E. coli* O157:H7, a scientific basis is necessary to justify why any raw ground product produced at the grinder from those source materials should not be considered adulterated. Such a scientific basis could include establishment test results in which the establishment tested each lot for *E. coli* O157:H7 using a robust sampling and testing plan and found the other lot negative for *E. coli* O157:H7.

Alternative lot definitions

In addition to the parameters described above which can be used to define the sampled lot, FSIS has provided establishments that have their own sampling and testing programs the option to reduce their lot size for beef manufacturing trimmings, other raw ground beef components, or raw ground beef products **to one combo bin or other unit** (e.g., box) on the day that FSIS conducts sampling provided that the establishment:

1. Has a **validated intervention** for *E. coli* O157:H7 at a Critical Control Point (CCP) in the HACCP plan that covers the product or requires an intervention for *E. coli* O157:H7 at a CCP for that product's source materials; and
2. **Samples and tests every production lot for *E. coli* O157:H7** and generally collects its samples of beef manufacturing trimmings, other raw ground beef components, or raw ground beef products across multiple combo bins or other sample units.

If an establishment meets these criteria and reduces its lot size to a single combo bin or sample unit when FSIS samples the product, then FSIS will collect the sample from the single combo bin or unit.

Establishments may also have written procedures to grind a minimum batch of product that represents the entire lot in a smaller grinder. To ensure that the sample is representative of the lot, establishments with these written procedures need to have supporting documentation that describes how the minimum batch is representative of the entire lot (e.g., includes an appropriate proportion of all types of trim used to produce the lot). As a general guide, the minimum batch size should not be less than 50 pounds. In order to reduce the sampled lot to this minimum batch size, establishments will need to meet the 2 criteria listed above.

Determining the Sampled Lot for RTE Products Subject to Listeria monocytogenes and Salmonella Testing

A production lot for ***RTE product*** is typically defined as all product produced from clean-up to clean-up unless the official establishment can support a smaller lot size. Unlike *E. coli* O157:H7 and non-O157 STEC, *Listeria monocytogenes* (*Lm*) primarily contaminates product from the production environment. Therefore, it is difficult for establishments to support that *Lm* did not contaminate all product produced since the last complete clean-up. If the establishment performs a complete cleaning and sanitizing (following the procedures in its Sanitation SOP) between lots, the lot size could be reduced.

Considerations that should be taken into account when determining lot size include RTE source materials used, frequency of cleaning and sanitizing, and processing steps employed. An example of RTE source materials would be the chicken used in a chicken salad. If the chicken is received from another establishment, and product from

the same bag or container is used in multiple lots, then the establishment should consider whether microbiological independence is maintained between lots. If one of the lots containing a common RTE source material tests positive by FSIS, a scientific basis is necessary to justify why the other lots should not be implicated (for example, the source material was not the cause of the positive). Establishments should also consider whether the re-use of brine between lots would affect microbiological independence. In addition, establishments should consider how processing steps affect microbiological independence between lots. For example, since *Salmonella* contaminate RTE products as a result of under-processing, if one lot of RTE product tests positive by FSIS, and another lot of product received the same lethality treatment, a scientific basis is necessary to justify why the later lot should not be implicated.

NOTE: An official establishment may reduce its lot size on a day when FSIS collects a routine RTE sample, in order to facilitate holding the product, as long as the change does not interfere with FSIS's ability to collect a representative sample. For example, decreasing the lot size could impact FSIS's ability to collect the samples because *Listeria monocytogenes* works its way out of the equipment after 3 hours. As a result, if the establishment produces a very small lot on the day FSIS collects a sample when it typically produces a larger lot, then FSIS may not be able to collect a representative sample.

KEY QUESTION

Question: If an establishment produces two lots of RTE product from the same source materials, and FSIS test results from one lot of product come back as unacceptable (e.g., positive for *Listeria monocytogenes*), will the second lot of product need to be recalled if it was released into commerce?

Answer: It depends. If one of the lots containing a common RTE source material tests positive by FSIS, a scientific basis is necessary to justify why the other lots should not be implicated. For example, the establishment may be able to support that source materials received a lethality treatment in the final package. Therefore, post-lethality contamination with *Listeria monocytogenes* would not be possible.

Products produced in the same room could be considered part of the same or different processing lots, depending on how the lots are separated. If the processing lines can be considered microbiologically and physically independent of one another (i.e., equipment, personnel, utensils, and RTE source materials are not shared among the lines), then they can be considered different lots. Likewise, products produced on the same line could be considered different processing lots if they are separated by a complete cleaning and sanitization, as well as the other factors described above.

NOTE: Products stored in a common cooler would not necessarily be considered part of the same lot. However, the establishment's Sanitation SOP

should address possible cross contamination, especially if RTE and raw products are held in the same cooler.

The guidance provided for determining the sampled lot for RTE products subject to *Listeria monocytogenes* and *Salmonella* testing can also be applied to determining the sampled lot of product when FSIS collects a food contact surface (FCS) sample for *Listeria monocytogenes* or *Salmonella*. Product that passes over the tested FCS will also need to be held pending test results because the product would be considered adulterated if it passed over a FCS that tested positive for *Listeria monocytogenes* or *Salmonella*. As with product samples, products produced in the same room but on different processing lines could be considered part of the same or different processing lots, depending on how the lots are separated. If a FCS tests positive on one line, and the establishment has supporting documentation that there is not cross contamination among the lines, then lots produced on the other lines may not be implicated.
The guidance provided in this section can also be found in Chapter 3, Page 15 of the **revised** *Listeria* Guidelines available at http://www.fsis.usda.gov/PDF/Controlling_LM_RTE_guideline_0912.pdf.

Determining Product Held for Livestock Carcasses Subject to Residue Sampling and Testing

For chemical residues, only the sampled livestock carcass is typically held. That is because for chemical residues, lots typically are determined on a carcass basis during the slaughter operation, unless there is evidence of flock or herd application of the treatment. Although not required under this new policy, it is also recommended that establishments hold the specific poultry carcasses that are sampled for residues.

Guidance for Importers of Record on controlling meat and poultry products pending FSIS test results

What imported products are subject to this policy?

Under the new policy, the following products tested by FSIS cannot move into commerce until acceptable results become available:

- Raw, non-intact beef or veal products such as ground beef, hamburgers, and patties and raw products that are components of non-intact products including beef manufacturing trimmings, bench trim, heart meat, head meat, cheek meat, weasand meat, product from Advanced Meat Recovery (AMR) systems, low temperature rendered lean finely textured beef (LFTB), partially defatted beef fatty tissue, and partially defatted chopped beef tested for *E. coli* O157:H7 and non-O157 Shiga-toxin producing *Escherichia coli* (non-O157 STEC);
- Ready-to-eat (RTE) products tested for *Listeria monocytogenes* and *Salmonella;*

- Livestock carcasses and other products **other than raw poultry carcasses and parts** subject to FSIS testing for residues; and
- Products that are tested for non-food safety consumer protection verification (e.g., protein-fat-free and moisture in hams).

The policy does not cover:

- Raw meat or poultry products that FSIS has tested for *Salmonella* or other pathogens (such as *Campylobacter*) that FSIS has not designated as adulterants in those products and
- Poultry carcasses **or other raw poultry parts** subject to FSIS testing for residues and pesticides.

Can an importer of record move product from the official import inspection establishment pending receipt of final laboratory results?

Yes, the importer of record can move imported product off-site from the official import inspection establishment provided the importer has controls in place that will ensure that product does not enter commerce until the importer of record receives notification of acceptable test results.

> **NOTE:** The policy regarding product assigned reinspection at the Intensified level has not changed. Lots of imported product that are assigned reinspection at the Intensified level are under FSIS hold and are not permitted to move off-site from the official import inspection establishment.

What does FSIS consider adequate controls when product is moved from the official import inspection establishment prior to receipt of laboratory results?

Importers of record are to maintain the integrity of the lot and may use any effective mechanism to control the product, including the use of company seals. The Agency will require importers of record to document that they can control the product pending the availability of test results and provide that documentation to FSIS personnel prior to moving the shipment off-site.

When will FSIS consider imported product to be in commerce?

If the movement of product results in a change of ownership from the importer of record that presented the product for FSIS reinspection at the official import inspection establishment to any other entity prior to receipt of laboratory results, or if the importer of record relinquishes ownership of the product before receiving the laboratory results, then the product is considered to have entered commerce. Both of these actions are violations of the test and hold provision. Therefore, the product may be subject to redelivery by Customs and Border Protection (CBP) or local Customs authority and to

any fines or penalties imposed by such authority, as well as to enforcement actions by FSIS.

> **NOTE:** FSIS defines the importer of record as the named individual or company on the entry made with CBP or the local Customs authority.

What actions will FSIS take on imported product that receives an unacceptable laboratory result?

When the importer of record has maintained control of the product, and unacceptable results are reported, FSIS will refuse the product entry. The importer of record must make appropriate arrangements with FSIS to return the product to an official import inspection establishment to have the product marked as U.S. Refused Entry. The importer of record still has the option to re-export refused entry product.

When the importer of record has NOT maintained control of the product, or ownership has changed, and unacceptable results are found, the importer of record has shipped adulterated product into commerce as the product is considered to be domestic product and is subject to recall. In addition, adulterated product in U.S. commerce is no longer eligible for re-exportation, and the importer of record is subject to FSIS enforcement action or sanctions, as appropriate.

What is the minimum amount of time product will have to be on hold or under control for pending FSIS test results?

The following table summarizes the minimum number of days from receipt to when the result is received depending on whether the result is determined to be acceptable or unacceptable by analysis type.

Analysis	**Minimum Number of Days from Receipt When the Result Is:**	
	Acceptable	***Unacceptable***
E. coli O157:H7 and non-O157 in raw beef products	2	4
Listeria monocytogenes in RTE products	3	6
Salmonella in RTE products	1	5
Residue (antibiotics, sulfonamides, or avermectins or the feed additive carbadox) and pesticides in livestock and poultry other than raw poultry carcasses or parts	4*	Will depend on what is screened and the number and type of additional analyses required
Non-food safety consumer protection	Will depend on the type of analysis	Will depend on the type of analysis

verification		

**Does not include the time (12 – 24 hours minimum) it takes to freeze the sample prior to shipping to the laboratory.*

FSIS begins testing of all raw beef and RTE products for microbiological pathogen analysis or for residues the day of receipt, including Saturdays. Non-food safety consumer protection verification analyses are started Monday through Friday on the day of receipt; analysis of non-food safety samples received on Saturdays are started on Mondays. In regard to sample discards, any sample that the FSIS laboratory may discard would occur the day of receipt and would not increase turnaround times in any way. Official import inspection establishments can receive lab sample results from the Agency electronically.

More information on the various FSIS laboratory methodologies including time-frames for receipt of results can be found in the Microbiological Lab Guidebook and the FSIS Analytical Chemistry Laboratory Guidebook available at: http://www.fsis.usda.gov/Science/Guidebooks_&_Methods/index.asp.

How does an importer of record determine the amount of product he or she needs to hold?

The sampled lot is the product represented by the sample tested by FSIS, which is the defined lot on the foreign inspection certificate. As with domestic product, for lotting purposes, lots are defined so that if a positive result is found on one lot, the product from the other lot would not be implicated. Two such lots are called independent or microbiologically-independent lots. A lot of imported product is determined by the information provided by the foreign inspection system on the foreign inspection certificate and cannot be altered at point of entry reinspection. Therefore, it is critical that the importer of record work with the foreign establishment in regard to how product is lotted.