

Industry Best Practices for Holding Tested Products

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Introduction

This document was designed to develop and discuss best practices that can be used throughout the food production system to ensure that products being tested for pathogens or other adulterants are held until results are received. This document outlines key issues that may assist establishments in developing plant-specific procedures. This document is not designed to require the use of any specific system, but stresses the importance of knowing that optimal results can be reached based on the plant's specific system. All of the information provided in this document may not apply to your specific operation, and some of the items may work better than others for a specific operation. Therefore, operators should customize the best practices to make them fit their individual operation.

Holding product while test results are pending is a good business practice. Test and hold procedures for finished product should not be used to determine product safety. However, testing is a type of verification activity and should be used appropriately. The goal of this document is to provide information which, if implemented by establishments, will prevent products from entering commerce that have pending tests for pathogens or other adulterants, which should then decrease the number of recalls associated with positive results.

Industry Best Practices for Holding Tested Products

To develop and implement the optimal system for testing and holding products, establishments must carefully consider the specifics of their operation. When a plant-specific test and hold program is in-place, establishments should have control over the product and prevent a recall if test results are positive for pathogens or other adulterants. Effective practices for identifying and holding products should be used when the establishment is conducting the testing and when United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) or another government agency takes a sample. Customers may request product testing. However, establishments should work with customers to ensure that the product can be held pending the test result.

This document includes considerations for establishments producing raw products and those producing ready-to-eat (RTE) products. Establishments can use this document to develop plant specific programs.

Raw Products

Because *E. coli* O157:H7 is an adulterant in beef intended for grinding, raw, ground beef, and non-intact beef products, it is important that producers of raw beef products consider the factors that may impact the types and/or amounts of product affected by a positive *E. coli* O157:H7 test result. For ground beef, one issue to consider is the raw material(s) being used to produce the finished product. If the same source materials are used in more than one lot, all lots produced

with the common source material may be affected by a positive *E. coli* O157:H7 test result. Establishments must identify lots and have a system for product traceability throughout the operation. The following items may be considered:

1. Raw Materials

a. Fresh vs. Frozen Shelf-life: Fresh product may have a shelf-life requirement that prevents you from holding raw materials for multiple days while you wait on a test result. Frozen product may provide more flexibility regarding holding product.

b. Quantity and Use: Raw materials may be purchased for use in one product or they may be used in multiple products. They may be used on a single production day or spread across multiple production days. If a test is planned, consider scheduling the use of raw materials to ensure a clean separation between the tested source materials and untested source materials.

c. Supplier Identification: Establishments that purchase from multiple suppliers may want to develop a system for identifying and tracking raw material based on supplier.

d. Lot Identification: Establishments should have a process for accurately identifying the lot of product that would be impacted by a positive test result. The lot definition may take into consideration the items listed above. The lot identification may include raw material supplier(s), production date of raw materials, amount of material(s) used, data from pre-screen testing, and other data. It is important to note that the lot/source of the raw materials can be questioned if there is a positive test result. Therefore, all source material within the same identifiable lot should be held until the test result is received. If the same raw source materials are used in more than one lot, then all lots produced with the common materials could be affected by a positive test result. Unless the establishment can demonstrate that all of the lots produced would not contain the pathogen, then all of the lots could be subject to recall. Therefore, it is very important that source materials, and any interventions used to eliminate *E. coli* O157:H7 on source materials are clearly identified and carefully considered when determining which lots/products would be impacted by a positive test result. An example form for identifying lots is attached. (Attachment 1).

e. Establishment Generated Trim: One practice is to not use in-plant generated trim to produce raw ground beef, but rather to sell it to fully-cook operations. However, for a facility that includes this trim in the ground products; it must comply with all of the *E. coli* requirements outlined in October 7, 2002, *Federal Register* Notice and FSIS Directive 10, 010.1.

<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/10.010.1.pdf>

Summary of actions to consider for raw products

1. Freeze tested finished products to ensure longer shelf life pending test results.
2. Using a single, or limited number of suppliers and/or lots of raw materials and conducting cleaning and sanitizing following the sampling may reduce the amount of products that need to be held. (Please note: If you normally grind raw materials from multiple suppliers and only grind a single supplier when being sampled, the Agency may elect to take additional samples.)
3. Develop a system for identifying and tracking raw material by supplier.
4. Develop a system to identify the tested lots, as well as, all associated source material.
5. Control and track the use of trim generated on the day of a product test by diverting trim to cook processes or following plant procedures for raw processes.

Ready-to-Eat (RTE) Products

Producers of RTE products should ensure that their lethality process is valid. For example, if a company is using Appendix A then it must follow all components of the lethality guideline — temperature, time, and relative humidity. *Salmonella* and *Listeria monocytogenes (Lm)* are adulterants in RTE products. If FSIS or a state inspection agency samples a RTE product for pathogens, those agencies will usually test for both *Salmonella* and *Lm*. The implications of a positive test result may require different considerations, so the two microorganisms are discussed separately.

Salmonella

- a. Positive *Salmonella* results in RTE products are most often the result of failure to achieve lethality. However, other circumstances might exist that require a plant to consider other areas for contamination.
- b. Establishments must define production lines to identify impacted product. For example, is production a continuous system or is it a batch system? Are multiple production lines and/or products involved if there is a lethality failure? In order to minimize a potential recall, the establishment should be prepared to identify why or how one lot with a positive test result may have had inadequate lethality while records will support that prior lots were acceptable. An establishment should consider post-lethality parameters, if applicable.
- c. Establishments may want to document the plant procedures for producing RTE products. Documentation should include: cook temperatures, oven/equipment settings, operational SSOP information, employee product handling procedures, maintenance records on RTE lines and equipment. This information may help identify products that would be involved if there is a lethality failure.

Listeria monocytogenes

a. *Lm* is most often the result of post-lethality contamination. Producers of RTE products should refer to the FSIS Compliance Guidelines to Control *Lm* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products for additional information.

http://www.fsis.usda.gov/oppde/rdad/frpubs/97013f/lm_rule_compliance_guidelines_2004.pdf

b. Define product(s) that would be impacted by a positive test result and develop a system to document establishment practices. Items to consider:

1. Production Lines — are there multiple products being handled on a single production line or being processed in a single processing room? If so, ensure a means of identifying why each line is a different lot.

2. Equipment — is the post-lethality equipment (i.e., slicer, table, packaging equipment, etc.) used for multiple products or are there common surfaces for multiple products? Avoid shared equipment wherever possible or ensure that all product associated with that equipment is considered part of the same lot and would be placed on hold pending the test result.

3. Employees — does the employee traffic flow allow separation of products or does it possibly impact additional product (i.e., same employees handling multiple RTE products)? Ensure that employees who move from one line to another change gloves and outer clothing, as necessary.

4. Environmental Contamination — is there sufficient documentation pertaining to cleaning and sanitizing between production days or lots? Are negative results available to indicate that any identified contamination is limited to one line or piece of equipment. Have there been repetitive environmental sampling positives and if so were appropriate actions taken and documented?

c. Are multiple products produced under a single HACCP plan, and if so can the establishment separate production lines or schedules to identify impacted products?

d. Establishments should document the following information to assist with lot identification and product traceability: line and/or location in processing room, date and time of production; quantity of product produced; lot code or product identity for product being tested; production shift; product label or common name of product. (**Attachment 2**)

e. Establishments that produce multiple component RTE products (e.g., sandwich, burrito) or add ingredients (e.g., sauce, glaze) post-lethality should have data to support the use of the other components/additional ingredients. It is important to know the impact it may have if these components/ingredients are the cause of the *L.m.* positive in the finished product. Establishments should obtain data from the producing establishment regarding validated lethality, environmental conditions, and any available pathogen test

results. In addition to the above points, establishments must understand that sanitation can be used to separate lots and reduce the amount of product involved in a recall, providing it is done properly. The cleaning and sanitizing procedures must be as effective as those performed as part of preoperational SSOPs. The establishment must be able to document the cleaning, sanitizing and reinspection activities to establish a break in production. (Example Holding Tested Product Form is provided in **Attachment 3**).

Summary of actions to consider for RTE products

1. Ensure validation and documentation of lethality procedures.
2. Define the tested lot or line based on the lethality step.
3. Document procedures clearly defining the lethality step.
4. Review and follow compliance guidelines to control *Listeria* in the environment.
5. Define the tested lot by line, equipment, employees, and other environmental considerations.
6. Define the lot based on the HACCP plan.
7. Clearly identify the lot using detailed documentation.
8. Evaluate and document the potential introduction of pathogens from other sources (multi-component products).

General Points for Hold and Test Programs

The following considerations apply to all operations that are testing products for pathogens or other adulterants and can be used to develop an effective test and hold program.

1. *Communication with Inspection Personnel*: Effective communication with inspection personnel is critical to the success of a test and hold program. Establishments should conduct an “informational” meeting with the inspector after a plant specific test and hold program has been developed. The information may also be shared with the district office. The following items should be discussed with the inspection personnel and the meeting should include inspection personnel from all shifts.

a. Discuss products being produced and the lotting/production system in place for each product that may be subject to pathogen testing. Make sure that the agency personnel understand what a sample represents (e.g., use of raw materials over multiple days for a grinding operation; separation of product lines for a RTE operation). Remember, it is the establishment’s responsibility to determine and support its decision on the amount of product that will be held. The Agency personnel’s role is to provide Agency regulatory or policy guidance.

b. Provide justification for the amount of notification time needed prior to the agency taking a sample to control the affected lot/product and to maintain normal business practices (e.g., use of same source raw materials used for multiple days in a grinding operation that produces fresh products that are delivered daily; time

that the sample is pulled and the impact on production). Some establishments may require advance notification to provide the establishment adequate time to hold all products represented by the sample. Plant personnel should be able to support their request for advance notification based on the type of product being produced, the raw materials being used, and the production process. Prior notification should be used to ensure appropriate holding of raw materials and finished product associated with the test.

c. For RTE products, there should be a discussion of the environmental sampling program and the use of the results in conjunction with holding tested product procedures for products produced in Alternatives 2 and 3.

d. Discuss advantages and procedures for holding product (e.g., reduce recalls or limit the scope of a recall; product held on-site vs. off-site).

e. Discuss any routine pathogen testing that is conducted by the establishment and the procedures for holding the product, as well as the procedures for product disposition if the product is positive for pathogens. Procedures for holding product or raw materials should be consistent for company testing, customer testing, and FSIS testing.

The informational meeting should be documented, identifying who attended (both plant and agency personnel), date and time of meeting, and a summary of items discussed. (An example document is provided as **Attachment 4.**)

2. *Test and Hold Planning:* A test and hold plan should:

a. Include a written detailed plan that includes plant-specific procedures to be used to implement an effective program;

b. Include a tracking and documentation system that identifies the product(s) placed on hold, and the release or appropriate disposition process upon receipt of test results;

c. Provide written justification for production issues (e.g., raw materials, product shelf-life, physical space to hold product, ability to fill customer orders, line separation) to support the requested notification time prior to agency sampling; and

d. Be reviewed periodically to ensure adequacy and to modify as needed.

3. *Physical Control of the Product(s) Held:* A test and hold plan should:

a. Provide an easily identified system of marking/tagging products held to distinguish them from other products. Examples of identification systems include: use of color-coded shrink-wrap, use of color-coded tape (like crime scene tape), or use of color-coded tags;

b. Address the tracking of product held (e.g., where is it located, if transported offsite – carrier, delivery information, location at off-site storage);

- c. Provide for the use of tamper-resistant seals, especially if the product is stored off-site; and
- d. Document product control while it is held.

4. *Limited Physical Space*: Establishments with limited physical space on-site to hold product may:

- a. Store the product at an off-site location providing complete control of the product can be maintained during transport and at the off-site location;
- b. Develop a written procedure for off-site holding that includes a signature from the off-site location indicating that the establishment is in control of the product and that if the pathogen test result is positive that removing it from the off-site storage will not be considered a ‘recall’ of product because it was not “in commerce;”
- c. Produce a limited amount of product to reduce the amount held; and d. Maintain records of all products held at off-site locations.

5. *Maintaining Control of Product(s) being Held*: Establishments should have procedures to prevent products being held from entering commerce.

- a. If possible, store the product being held away from other products.
- b. Clearly identify the product being held to distinguish it from other products to prevent it from being shipped accidentally.
- c. Protect unpackaged product from cross-contamination.
- d. Track the location of the product being held during storage and transportation.
- e. Use tamper-resistant, numbered seals, especially when storing the product being held offsite.

6. *Product with Limited Shelf-life*: Establishments that produce products with limited/short, shelf-life may limit the amount of product held by stopping production after the sample is taken by conducting a complete cleaning, sanitizing and documented reinspection, and restarting production.

- a. If additional production is occurring in the processing room, it is best to wait until production is completed to conduct cleaning and sanitizing to prevent contamination. The equipment associated with the pathogen test needs to be cleaned and sanitized prior to use or tagged/identified to prevent it from being used through the rest of the day until cleaning and sanitizing can occur. It is important that these procedures are documented.
- b. If producing a raw, ground product, restart production using a different supplier/lot of raw materials than was used when the sample was taken.

7. *Production Lots and Raw Materials*: Test and Hold programs should:

- a. Clearly identify and document the establishment's procedures for lotting raw materials and finished products.
 - For raw ground beef, consider using a separate supplier or separate lot of product from that being tested.
 - For RTE products, identify separation of production lines/areas and use of cleaning and sanitizing procedures to break lots.
- b. Document use of raw materials and processing of products to provide a system of traceability.

8. *Filling Orders*: To assist with filling orders, establishments can:

- a. Make an additional lot of product large enough to compensate for the tested lot. This can be done prior to sampling, if sufficient notification is given, or following the sampling if proper cleaning/sanitizing and lot separation is maintained.
- b. When practicable, alternate lots may be available to prevent holding of all product produced.
- c. If possible, establishments may have co-packers fill orders for them. Agency labeling policy does accommodate such arrangements.
- d. Work with inspection personnel to ensure that their notification process adequate time for the establishment to hold all affected product(s). The specifics regarding when a sample is to be taken and which specific products will be collected are the responsibility of Agency personnel.

9. *Recordkeeping*: Test and Hold programs should:

- a. Provide a written, detailed description of the entire test and hold procedure;
- b. Ensure control of the product(s) being held;
- c. Include a written agreement with all off-site storage facilities used to store product while it is being held pending test results;
- d. Document Certificate of Analysis (COAs) and any test results for any raw materials being used in raw, ground product;
- e. Document COAs, any test results and letters of guarantees from suppliers of multi-component RTE products;
- f. Provide a documentation system that:
 - Identifies product(s) being held
 - Includes date and time of sample collection
 - Includes product name

- Includes raw material information
 - Includes production or lot code
 - Includes product volume
 - Includes plant contacts
 - Includes the release of product or appropriate disposition
- g. Document sanitation and reinspection procedures designed to ensure the separation of product runs or production lines.

Summary

Although testing is not a control to make products safer, it is requested by customers and required by FSIS. Customer requests should be thoroughly discussed, encouraging the customer to evaluate environmental results for potential *Lm* issues and intervention validation for *E. coli* O157:H7 rather than relying solely on product testing. These types of data can be more valuable than a product test. If product testing is done, an effective hold and test program is essential to minimize recall of tested product. Establishment personnel and inspection personnel should work together to ensure that a holding program will be successful and help accomplish the overall goal of food safety. Advance planning, communication and understanding the purpose of product testing will achieve a reduction in recalls and enhance public confidence in the food industry's management practices.

ATTACHMENT 1

Lot Identification Form

Date Received	Type of Product	Source ID (Establishment Number)	Amount of Product in the Lot	Production / Code Date on Product	Date(s) Used in Production	Signature

ATTACHMENT 2

Lot Identification and Product Traceability Log

Production Date	Production Time	Processing Line or Room Identification	Quantity of Product Produced	Lot Code or Product Identity	Product Label or Common Name

ATTACHMENT 3

HOLDING TESTED PRODUCTS — CHECKLIST

Product Sample Date: _____ Product Description: _____ Item No. _____

Production Date: _____ Sell by date: _____ Lot Code: _____ Temperature: _____

Tasks to be completed upon notification that a sample will be taken for pathogen testing:

Tasks:	Done	Comments:
1. Inform all employees not to move to other packaging lines unless they completely change aprons gloves and conduct a complete hand washing and other sanitary activities.		
2. Inform employees not to share utensils, rework tubs, etc. from the sampled lines with any other lines.		
3. Assure line specific coding is in place.		
Hold Procedures:		
1. Place all affected product from the HACCP plan and the packaging line sampled on hold.		
2. For ALL items in the packaging room, verify the following in all pertinent HACCP records:		
All cooks times/temperatures were adequate.		
All monitoring activities were completed accurately.		
All verification activities were completed accurately.		
Any needed corrective actions were handled properly.		
All equipment calibration activities were completed accurately.		
All record keeping activities were completed accurately.		
3. Verify no Pre-Operative checks/activities revealed any situations that could contribute to cross – contamination.		
4. Verify no Operative checks/activities revealed any situations that could contribute to cross contamination.		
5. Verify no NRs revealed any situations that could indicate any cross-contamination occur.		
If this sample is to be pulled by FSIS:		
Review the above results with the IIC and reach agreement that there were no known situations indicating any cross contamination. (Note: Your IIC may not be willing to do this, but review the information with him/her anyway.)		
6. Verify that cleanup and resanitizing of all equipment and utensil occurs after completion of test lot and before starting of another lot.		
7. Verify that all employees wash and change aprons, sleeves, gloves before starting another lot.		
Completed by: _____	Date: _____	Signed: _____

ATTACHMENT 4

Holding Tested Products — Informational Meeting with FSIS Personnel

Date: _____ Time: _____ a.m / p.m.

Plant Personnel in Attendance:

Agency Personnel in Attendance:

Summary of Items Discussed:

1. _____

2. _____

3. _____

4. _____

5. _____

6. _____

Attach additional pages as need to document discussion.