
# Guidance for Purchasers of Raw Beef for Non-Intact Use

November 2016

The following is designed to assist purchasers of raw beef intended for grinding or other non-intact use in maximizing the food safety of the raw materials and finished products, as well as meeting Food Safety and Inspection Service (FSIS) requirements. This guidance will address written purchase programs, incorporation of purchase programs into the HACCP plan, and considerations for testing by purchasers.

Every purchaser of raw beef must have a written purchase program for all raw meat used in any non-intact process, such as grinding, mechanical tenderization, injection and vacuum tumbled/marinated. The program must address basic components which support that supplier and purchaser have agreement on the food safety and regulatory requirements of the sale. The purchase program must be considered as part of the purchaser's HACCP plan.

Finally, raw beef purchasers must carefully consider testing programs. These programs will vary depending on supplier documentation, product type, and purchaser's food safety programs. This guidance will provide considerations for developing a plan for testing when applicable.

**Purchase Program**

The Purchase Program overall must address the hazard of *E. coli* O157:H7 and the other adulterant Shiga Toxin-Producing *Escherichia Coli* (STEC).[1] As to Non-O157 STEC, FSIS has expressly recognized that an establishment can determine its controls over *E. coli* O157:H7 would be effective for the non-O157 STEC. This negates the need to have separate provisions for non-O157 STEC, "unless data such as multiple non-O157 STEC sample results at a given establishment indicate otherwise." As such, for the remainder of this document "STEC" will be used to indicate *E. coli* O157:H7 and Non-O157 STEC. Purchasers of imported raw beef intended for grinding or other non-intact use will need to take into consideration USDA equivalency declarations and address the hazard of STEC accordingly.

The written Purchase Program, has three basic components: a Letter of Guarantee (LOG) from each supplier; Certificates of Analysis (COA) for the raw materials intended for non-intact use, or a recognized alternative to a COA; and on-going communication between the receiving establishment and the supplier, either directly or through the supplier's website.

***Letter of Guarantee (LOG)*** The letter of guarantee must describe the supplier's food safety system, especially as it relates to STEC controls. This would include, but is not limited to:

- Acknowledgement that the supplier's HACCP plan addresses STEC,
- A description of the interventions used by the supplier,
- Identification of the validated CCP or CCPs to address STEC (at least one CCP is required),

[1] For this Guidance, STEC will include both *E. coli* O157:H7 and the six adulterant non-O157 STEC: O26, O45, O103, O111, O121, and O145.

- The details of the establishment's testing programs, including sample collection technique (N60 or other method) and testing procedures (*e.g.*., GDS, BAX, IEH, etc.), which must be equivalent to FSIS's program,[2]

- Acknowledgement that the supplier has a high event period (HEP) program, which includes, in part, consideration of primals during high events,

- Whether there is commingling of intact products and, if so, whether the commingling is negated with an intervention,[3]

- A statement describing the relationship between primals and trim, e.g., primals receive same interventions as trim, or primals receive an additional intervention on the fabrication floor, and

- How the supplier conducts on-going verification, such as with third party audits and verification samples.

The LOG can be provided to the purchaser directly or can be obtained from the supplier's website.

***Certificate of Analysis (COA).*** Trimmings and other raw beef components intended for grinding are most often accompanied by a Certificate of Analysis (COA).[4]

In assessing the adequacy of the COA, the purchaser must ensure the results would be recognized by FSIS. This looks to:

- The number of samples selected for the analysis:
    - For product in combos (unpackaged), at least sixty (60) samples should be taken from separate pieces of meat, taken equally from all combos in the lot covered by the COA.
    - FSIS has recognized equivalent sampling methods to 60 samples. Verify the sampling method has been approved.
    - For product in boxes, at least 60 samples in the defined lot taken from separate boxes.

- The location of the sampling: the samples should be taken from the exterior surface through excision or an equivalent method.

- All pieces in the sample must be analyzed. The weight of the sample analyzed must be at least 325 grams. A smaller amount has been recognized by FSIS with alternative sampling methods (see Section V, page 8, Compliance Guidelines for Establishments…)

[2] See discussion as to adequacy of testing programs in the section discussing certificates of analysis directly below.

[3] See discussion on sampling individual cryovaced product and commingling on pages 7 and 8 below. In the event commingling is not in the log, the purchaser can obtain the assurances from the supplier's website or through some other form of documentation.

[4] For head/cheek meat, the supplier does conduct testing of the production, but the lot is typically an entire period, shift, or day. Since purchasers do not purchase the entire lot of head/cheek meat, the supplier will not send a COA which would apply only to the entire lot, but will send a letter stating that the product sent was part of a tested lot.

- The sample method:
    - The method used must be validated for *E. coli* O157:H7 or STEC (if analysis run on STEC) for the product being analyzed and meet the FSIS criteria of ≥98% sensitivity and ≥90% specificity.
    - In the case of Non-O157 analysis, FSIS has provided a list of methods that have received a no objection letter from the agency on its website. If the supplier's laboratory is not using one of these methods (or you are not sure), ask the supplier to clarify.

***Options to COA.*** There are times when a receiving establishment does not receive a COA. This may happen if the establishment purchases intact product that the supplying establishment did not intend to be used for non-intact product, such as cryovaced (vacuum packaged) subprimals. It may also happen if the product was subdivided from combos into boxes.

Just because the establishment did not receive a COA, does not mean the receiving establishment is required to test; there are options recognized by FSIS which the establishment can use to support that the STEC hazard is Not Reasonably Likely to Occur (NRLTO) at time of receipt. The establishment need only meet one of the options.

Option 1: Testing of Incoming Product

There are several options depending on the nature of the product purchased.

*Check Sample Program* – The simplest option, which applies to all product, is to rely on the "Check Sample Program." Under the Check Sample Program, the supplying establishment sends out trim or offal samples for verification that the process is in control and the testing program is adequate. These samples are taken minimally once per quarter in January - March and October - December and once per month in the other months (for a total of eight per year). The supplying establishment will post these results on its website or provide to the purchaser. If the receiving establishment is unsure whether the supplier performs a Check Sample Program, it should contact the supplier. If the supplier does have a Check Sample Program, all the receiving establishment needs to do is verify the results provided by the supplying establishment. [5]

*Testing Product Not Covered by a COA—Ground Beef* – Although raw materials intended for raw, non-intact use are generally covered by a COA, ground beef is not generally sampled, at least in small lots. It is customary that the sale of ground beef is accompanied by a statement on the sale documentation or within a LOG[6] that the ground beef was made from raw materials previously tested and found non-detectable for *E. coli* O157:H7. If not covered by a COA, the purchaser must be careful before adopting a sampling program at receipt because it is unlikely the purchaser will have all product implicated by the sample under its control. Accordingly, a positive finding will result in a recall of product from the same lot of ground beef distributed elsewhere. Given the absence of a regulatory mandate to sample purchased ground beef, the receiving establishment would be well advised to explore other options described.

[5] FSIS has recognized the use of a Check Sample Program. See FSIS Compliance Guidelines HACCP System Validation at page 52 (certificates of analysis or web based information that conveys same information).

[6]Sale documentation such as Bill of Lading is most often used by grinders; LOG is most often used by distributors.

Option 2: Antimicrobial Intervention

In the absence of a COA, Check Sample Program, and in lieu of testing, an establishment can treat the incoming product with an intervention validated to reduce STEC.

*Selecting an Antimicrobial* – The establishment needs to select an antimicrobial. FSIS Directive 7,120.1 lists a variety of substances which have received a No Objection Letter for use as an antimicrobial.

*Application of the Antimicrobial* – After selecting the antimicrobial, the establishment must develop procedures for application on products. This will involve identifying the operational parameters for the antimicrobial; a prudent establishment will work with the chemical manufacturer to identify the critical operational parameters. The establishment then needs to select and install the equipment to apply the antimicrobial to product. FSIS is especially interested as to whether the equipment provides complete coverage of the product with the intervention.

*Validation* – Even though listed in Directive 7,120, FSIS nonetheless expects the establishment to validate the intervention. **This does not mean testing for STEC**. For recognized antimicrobials, the establishment can validate by demonstrating that it comports with the critical operational parameters when the intervention is employed at the establishment and that complete coverage of trimmings or subprimals is consistently achieved (see FSIS Compliance Guidelines HACCP System Validation at page 53). If desired, establishments can use surrogate organisms to measure the efficacy of the intervention with a third party laboratory, university or an in house trained microbiologist.

Option 3: Testing of Finished Product

Should an establishment decide to test its own finished product, it must be careful so as to avoid a recall should the sample confirm positive. Since the purpose of testing is to verify the HACCP program, for the testing to be meaningful, the establishment must test its normal commercial product; in other words, the finished product it sends to its customers. Sampling a product it does not routinely sell, such as ground product made exclusively from a single ingredient (e.g., ox tails), does not represent the HACCP plan in operation and therefore does not verify the effectiveness of the HACCP plan. A review of sampling options are described later in this document.

***Continuing Communication with Supplier***

The third component of the purchase program is on-going communication with the supplier. This does not mean that the establishment must call its supplier on a weekly basis, but it does mean that the establishment obtains information from the supplier on an on-going basis.

Most commonly, information is conveyed via the supplier's website. The purchaser can obtain the web address from the supplier, from an internet search, or, in many cases, from the product labels. On the website, a purchaser can generally find:

- The LOG
- The intended uses of the various products

- The annual audits
- The results of the Check Sample Program

Any written purchase program should include a provision for checking all supplier websites for the above to ensure all documents are current and to view the results of the check samples. An establishment could check the website with the same frequency as the supplier uses to conduct its check samples – once per quarter in January - March and October - December and once per month in the other months (for a total of eight per year). The establishment should document the specifics whenever it checks a supplier's website to demonstrate compliance with this component.

**Incorporating the Purchase Program into the HACCP Plan**

Having developed the program, the next question is how to incorporate the program into the HACCP plan. It can be either a CCP or a pre-requisite program, depending on the determinations made in the hazard analysis.

If the establishment determines that STEC is a food safety hazard reasonably likely to occur, the establishment could designate the purchase program as a CCP, however, other options such as interventions may be more appropriate CCPs.

If the establishment determines that STEC is not a food safety hazard reasonably likely to occur, at least due to the operation of the program, the establishment could designate the program as a pre-requisite program.

In either case, the program must contain the three provisions discussed above:

- The supplier has provided a LOG which assures the supplier employs validated interventions addressing STEC,
- The products are accompanied by a supportable COA, or the establishment uses one of the three options, such as web-based information on check sample results, and
- Ongoing communication with supplier.

Compliance with all three components must be documented.

***Overview of Establishment Testing***

There are many considerations when determining whether and how the purchaser tests product.

First, there is no regulatory requirement that a receiving establishment re-test product covered by a COA. As discussed above, with a written purchase program, purchaser testing is not required for product received without a COA.

That said, if the purchaser chooses to conduct its own sampling, it must follow some basic rules of testing:

- Identify the product implicated by a sample:

- For ground beef, it is all product made from same lots of source materials and, in the absence of scientific evidence that a grinding system "cleans itself out," all product produced over the same food contact surfaces, clean-up to clean-up.
- For individually packaged subprimals, the individual piece of meat is the lot, provided there was no commingling (more than incidental meat-to meat contact following interventions) at the slaughter establishment and at the purchaser. The purchaser must have assurance that the supplier considers an individually packaged subprimal as a lot.
- If the supplier cannot supply assurance that the lot is an individually packaged subprimal, the purchaser must determine with the supplier what is the product implicated by a sample, prior to sampling.

- All product implicated by the sample must be under the establishment's control. Otherwise, a positive finding will result in a recall that may affect other establishments. In determining the product implicated, the establishment must consider whether the supplier distributed product from the same lot to multiple customers. A positive at one customer may result in a recall of the other customers' product. Purchasing split lots is not recommended.

- Properly collect the sample:
  - From surface of meat for all but ground; for ground, take five separate "grab samples,"
  - Ensure a sample of at least 325 grams is taken,
  - Follow aseptic sampling procedures, and
  - When sending to a laboratory, follow laboratory instructions for shipping product (*e.g.*, chain of custody and temperature requirement).

- Properly analyze the sample using a recognized method.

*Practice Tip*: If there is an initial screen test positive, the receiving establishment should proceed to confirm the sample using the FSIS cultural confirmation method at a laboratory accredited for STEC analysis.

For a more detailed description of Best Practices for Sampling, please see the Beef Industry Food Safety Council's (BIFSCo) 2016 "Guidance Document for Lotting and Sampling of Beef Products for Pathogen Analysis" which covers lotting and sampling of raw beef products, including cryovaced subprimals and ground beef, as well as selecting a laboratory.

*Practice Tip*: If you are unsure what product is implicated by a sample, **do not test and hope** for the best; ask for assistance from your trade association, BIFSCo, or an experienced consultant *before* testing. Failure to follow the considerations below may result in the supplying and/or receiving establishments, in addition to downstream customers, to unnecessarily initiate a recall.

Product Specific Considerations

*Testing Intact Product from the Supplier Not Covered by a COA and Intended by the Receiving Establishment for Use in Raw, Non-Intact Products* – As a general matter, an establishment

supplying individual packaged intact products does not intend those products to be used in the production of non-intact products. This intent may be conveyed in the LOG, through specific product codes, or on the supplier's web page. Once purchased, the receiving establishment can change the intended use to non-intact. However, by doing so, the receiving establishment must address the potential hazard in its own HACCP plan.

Should the purchaser decide to test the incoming product, it is possible to limit the raw material implicated to a single cryovaced package. According to askFSIS: a "further processor that receives individually cryovaced primals, sub-primals, or bench trim and uses or intends to use the product in raw non-intact product [can] support a lot definition consisting of one individually cryovaced product," provided "individually cryovaced product was not commingled at the supplier establishment (as represented through a purchase specification or some other form of documentation) and is not commingled or cross-contaminated, prior to sample collection." Ultimately, the purchaser should work with the supplier to support a lot definition before testing.

*Testing of Raw Ground Beef* – The total amount of product potentially implicated by a positive ground beef sample can be substantial given that a positive sample implicates all product made with the same lot of source materials, all product run over the same food contact surfaces, clean-up to clean-up, and all products containing rework from the implicated product.

Accordingly, FSIS permits two alternative sampling procedures. Under both, the establishment will randomly select the lot to be sampled in terms of day, shift, time, and product. Instead of drawing the sample on the line at that time, the establishment can use one of the two following alternatives.

- Grinding a minimum batch – An establishment may produce the ground beef on a smaller grinder provided the establishment has written procedures for such sampling, the smaller batch is representative of the establishment's production process, and the batch is at least 50 pounds. Attachment #1 provides a sample procedure and justification.

- Sampling the selected product at the start of production – An establishment may run the selected commercial product at the start of operations, then, following sampling, stop to conduct a pre-operational sanitation. When resuming production after a complete sanitation step, care must be taken to not include same source raw materials from the tested lot.

Under either alternative, the establishment must hold all products – the ground product and all the lots[7] of the source material used to produce the product.

***Note on testing portioned product***: According to an askFSIS Q&A, FSIS does not conduct testing on portioned product. Since FSIS does not conduct any testing on portioned product for its own verification activities, it follows that an establishment need not conduct verification sampling either. In such a case, the Check Sample Program would provide more than adequate

[7] The term "lot" means all units of the raw material covered by the same COA as the raw materials incorporated into the sample. If the COA covers one combo of trim, then that combo must be held. If the COA covers a 700-case load of imported product, then the entire import load must be held.

support to downstream customers.

***Note on Sample Selection:*** In selecting products to sample, the selection should be random, but not "mindless". Once a product has been selected for sampling, ***but*** before taking the sample, the establishment must determine whether any lots of raw source materials used in the product being sampled have already been used in other products that have left the establishment's control. If so, a positive sample will result in the automatic recall of products already made using the same source materials. If the establishment determines it has used implicated source materials, it must randomly select a different product that is not made from same source materials already used in other products. (This applies to samples selected for random testing and may not apply to samples collected for continuous / routine testing programs.)

*Testing of Non-Intact Products* – If the non-intact products are made from raw materials that were not accompanied by a COA, e.g., individually packaged subprimals, an establishment can test finished non-intact products. If the establishment samples finished non-intact products, the product implicated by a positive sample includes: any raw materials that were commingled (placed exposed in a vat or other container) with the raw materials used to make the positive product; other product run over the same equipment, clean-up to clean-up; and any bench trim made from the subprimals after any antimicrobial treatment (see below).

In terms of sampling itself, since the product is not comminuted, the sampling should be similar to sampling of trimmings – 60 samples from individual product totaling at least 325 grams, using excision or equivalent method, and analyzed with a recognized laboratory method.

*Testing of Bench Trim* – FSIS defines bench trim as trimmings derived from primals and subprimals that are not derived from cattle slaughtered at the plant. The rules applicable to trimmings generally apply with one important caveat: A positive finding in a lot of bench trim will implicate all products from which the bench trim was derived if those products are made into non-intact products. For example, if an establishment purchases subprimals, trims the subprimals to create bench trim and then uses the trimmed products for non-intact items, such as needle tenderized or injected, a positive on the bench trim will implicate the non-intact items. There is an exception to this – if the once trimmed intact items were put through a validated intervention after trimming and before being rendered non-intact, then the non-intact products would not be implicated. As a general matter, establishments generating bench trim in such situations either automatically send all the bench trim for cooking or hold the non-intact product until the results from the bench trim have been reported.

**Conclusion**

For establishments grinding or processing non-intact raw beef products, the safety of the finished product depends greatly on the safety of the raw materials purchased.

To maximize product safety, the establishment needs a sound written Purchase Program to ensure the suppliers have controls on their process and that the suppliers constantly verify that their controls are effective. The Purchase Program above, with its three components, has been recognized by industry and FSIS as the best continuing approach to addressing STEC in ground and other non-intact products.