Guide to E. coli O157:H7 Testing of Raw Ground Beef and Raw Ground Beef Components

Introduction

Since 1994, when *E. coli* O157:H7 was declared an adulterant in raw comminuted beef products, the Food Safety and Inspection Service (FSIS) has been testing raw ground beef for this pathogen. The general rule as to what product would be implicated by a positive finding ***had*** remained unchanged prior to this year.

Under the general principle, all product that ran over the same contact surfaces as the positive sample from clean-up to clean-up was implicated. This would include any "rework" initially produced on the sample day where it might have become contaminated and then used on subsequent days. This "rework" would implicate all raw product run over the same contact surfaces on these subsequent days, clean-up to clean-up.[1]

In 1997 a second principle was added: the "point source" rule. Under this principle, if a unit of raw materials – a single combo or a box – was broken up and used on different days and one of those days tested positive, any other days in which the remainder of the combo/box were used were also implicated – clean-up to clean-up.

In 2002, the agency's approach to this pathogen began to change – it was paying more attention to the raw materials used in ground beef. That year there was an 18 million pound recall of trim that had not been tested for *E. coli* O157:H7, but had been produced on a day when other combos had tested positive.[2] Also that year at least one recall (involving illnesses) was conducted based on the grinder's use of the same load of raw materials on different production days, even though the grinder followed the clean-up to clean-up and point source principles.

Changed Inquiry from Clean-Up to Clean-Up/Point Source to "Same Source Materials"

This year, FSIS issued its second set of Questions and Answers involving testing for *E. coli* O157:H7.[3] In the second question, FSIS rejected clean-up to clean-up as the means of identifying product implicated by a positive sample. Given its importance, the entire Q & A is reprinted in its entirety:

> 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

[1] Obviously, without some break, "rework" could technically contaminate subsequent products *ad infinitum*.

[2] Trim which had been tested and found negative was not included in the recall

[3] http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010_1/Directives_Q&A.pdf

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. (Emphasis added.)

Following this Q & A, clean-up to clean-up still remains relevant to the issue of possible cross-contamination of equipment, but it is no longer determinative. FSIS' focus is now the raw material; the "Same Source Materials" principle.

From a logical perspective, the agency's focus on same source materials makes sense, since the *E. coli* O157:H7 enters the ground beef through the raw materials (now called "raw ground beef components" by FSIS). Unfortunately, the change removes the certainty grinders previously had as to what product is implicated by an agency or establishment sample so that all implicated products could be held. This summer, a recall was initiated because the grinder did not take into account the same source materials when its own test of ground beef yielded a positive *E. coli* O157:H7; that establishment only relied on clean-up to clean-up/point source to determine the implicated product.

To assist both grinders and raw material suppliers, this Guide will explain the new "same source materials" principle. It will provide suggestions on how to minimize the amount of product implicated and how to avoid preventable recalls. Finally, it will summarize the principles applicable to the new FSIS National Trim Baseline, which includes testing of trim for *E. coli* O157:H7.

General Considerations Under the "Same Source Materials" Rule

As noted in the recent Q & A 2, the establishment needs to distinguish between "same source materials" to limit the amount of finished product implicated by a positive sample result. The agency does not specify precisely how to distinguish "same source materials;" rather that is left to the grinder.

The only currently acceptable way to distinguish same source materials is to test. So, there are three basic possibilities:

- The grinder lacks any test results – in which case the entire shipment of the particular raw beef component from the supplier will be deemed to be same source material.

- The supplier has tested the raw ground beef component and divided the shipment into "lots" or "sub-lots" – in which case, each individual lot or sub-lot would stand on its own, *provided*, the supplier has a sound basis for its testing program.

- The grinder itself has conducted extensive finished product testing – in which case, the establishment could segment the production day, *provided*, the grinder has a sound basis for its testing program.

Establishment Testing

For an establishment to limit the amount of "same source materials," all the raw material or the finished product must be tested. However, not all testing is created equal.

Raw Ground Beef Components

For raw beef components, three types of sampling regimes have been recognized by FSIS as providing a "sound basis" for separating tested product. Two involve excision sampling – the taking of surface samples from the trim or other raw components; the other involves core sampling.

On excision sampling, the establishment must take a significant number of surface samples. FSIS has recognized 30 and 60 samples per combo lot (generally referred to as N=30 and N=60 respectively). Indeed, as discussed in the section below on the FSIS National Trim Baseline, FSIS itself uses the N=60 method.

The core sampling is based on the requirements of a quick service restaurant. Under this approach, a "core gun" removes a column of meat from each combo (five cores per combo). The sample so collected is then composited with the samples from the other combos comprising the lot and analyzed for *E. coli* O157:H7.

Under all the methods, the "lot" is generally restricted to five combos or less, though some companies will include up to six combos per lot – to go further could dilute the sample rigor. This lotting and testing of combos provides the "sound basis" to distinguish one lot of combos from the other lots.

Most raw ground beef component suppliers use one of the sampling methods above for the beef trim. However, other raw materials used for comminuted beef products may not be tested. Although FSIS expects suppliers to test any component that is to be used in raw comminuted products, the producing establishment may not test a particular raw material if it does not have a reason to believe that the materials will be used in raw ground beef production. These materials could include heart, cheek meat, or fatty trimmings. Should a grinder intend to use such materials and is uncertain as to whether the material has been tested, the grinder is strongly advised to contact the producing establishment to ensure that these components are tested. Virtually all raw ground beef component suppliers will test these materials upon request. Since these raw materials are often used over several days of production, failure to obtain tested materials could end up implicating multiple production days if there is a positive *E. coli* O157:H7.

There is one other potential raw ground beef component which may not be tested by the supplier and needs to be addressed separately – boxes of vacuum packaged boneless beef (primarily sub-primals).[4] The vast majority of these products are used for a variety of purposes, but not for raw ground beef. Moreover, much of this product is routinely sold through distributors. So, the supplier

[4] We do note that most imported frozen boneless beef, domestic boneless beef in combo bins, and beef trim in boxes are routinely tested for *E. coli* O157:H7 as a matter of course. The above discussion relates to boneless beef in vacuum packages.

generally will not anticipate the vacuum package beef will be used for raw ground. Absent a direct contact with the supplier, it is unlikely a grinder will obtain tested boxed beef. If the grinder is currently using vacuum packaged boneless beef which is not tested, it should consider contacting the supplier to ensure the product the grinder is purchasing is tested. We anticipate that the boneless beef so tested would not be provided in vacuum packaging, but would be sent in the same manner as trim.

For completeness, we do wish to note that some grinders purchase course ground beef for fine grinding. In that case, the question becomes what testing the supplier is conducting. Some suppliers test the raw ground beef components used in the course grind. The principles above would apply to these products. Other suppliers conduct intensive testing of their coarse ground. The principles applicable to these products are discussed below.

Finished Raw Ground Beef Testing

To clarify one point up front on finished raw ground beef testing – neither the periodic verification sampling a company conducts nor FSIS sampling is sufficient to "lot" finished product. The magnitude of sampling must be greater.

To date, FSIS has recognized only one finished product sampling system to limit the amount of product implicated by a positive finding. The system, initially adopted as a requirement by a quick service restaurant, requires intensive sampling of finished product daily (either every 15 or 30 minutes of production). Four samples are composited (for every one hour or two hour period) and analyzed for *E. coli* O157:H7. If a single composite is positive, that "lot" is retained as well as the lots before and after the positive period. If there are multiple positive periods, the same rule applies (positive lot plus the lot on either side), though numerous positives could call into question whether the negative lots from that day are truly negative.

It is important to note that when an establishment conducts this intensive finished product sampling, FSIS does not impose the clean-up to clean-up requirement. The basis of this policy are studies and establishment data showing that *E. coli* O157:H7 is not an environmental contaminant; rather, it is introduced by the raw material and subsequent raw material will "clean the system out" in approximately one hour. See, ICMF book, Microorganisms in Food 7 (the contaminated raw materials cause a "comet-like" effect so that the contamination decreases over time to zero as the system cleans itself out). It should be emphasized that, as a general matter, FSIS will recognize this "comet effect" ***only*** if the establishment has been conducting sound, intensive testing.

FSIS Testing

The amount and nature of FSIS testing will likely change over the next few years. The agency has increased the amount of testing for *E. coli* O157:H7 in finished ground beef. It will also soon start testing trimmings for the pathogen. We anticipate that FSIS will maintain a level of approximately 10,000 tests per year, but that, as time passes, a larger percentage of those tests may be on trim and other raw ground beef components in lieu of finished product testing.

National Trim Baseline

FSIS has recently initiated its National Trim Baseline study.[5] The agency has already started drawing trim samples and beginning on November 28, 2005, it will begin analyzing those samples for *E. coli* O157:H7. If the trim tests positive, FSIS will ensure no trim product implicated by the sample is used for raw ground beef production.

As mentioned above, FSIS is using the N=60 sampling method whereby it will take 60 surface excision samples from a combo lot of approximately 15 grams each. From this 900 grams, FSIS will select 375 grams (the same sample weight as currently used for regulatory ground beef samples).

Under Notice 73-05, FSIS will take its sample regardless of whether the establishment has already cleared the product (*i.e.* has tested the trim and found it negative). This is being done to minimize the delay of waiting for the establishment and agency tests to be conducted sequentially, thereby preserving the value of the fresh trim.

If the establishment normally tests trim, the Notice provides that the agency expects the establishment to follow its procedures on the lot sampled by the agency. Indeed, the agency is very serious in its expectation that the plant will follow its normal procedures. Should the establishment sample test positive, the establishment must notify FSIS of the finding so that the agency's test result can be excluded from the baseline. This is because such trim would never have entered commerce for raw ground beef production.

It is important to note that FSIS recognizes that there will be times when a company test is negative and the agency's is positive (and *visa-versa*). In and of itself, this will not invalidate or otherwise call into question the company's testing methodology.

In terms of what product is implicated by a positive, the basic rule is that the combos tested by FSIS will be the only trim implicated, *provided*, the establishment can demonstrate that no other combos from that production day are implicated. The only basis currently recognized by FSIS to distinguish the other combos intended for raw ground beef is that the combos have been tested (and any combos testing positive have beef diverted to non-raw use). The approach adopted in 2002 by FSIS – "the agency will respect your negatives" – is still valid. Admittedly, it is uncertain what degree of rigor the establishment's sampling program must achieve to overcome any agency positive.[6] The apparent safe harbor would be one of the three sampling programs already recognized by FSIS: N=30, N=60, or core.

[5] At present, the baseline will be limited to trim. FSIS anticipates expanding the Baseline to include heart, cheek and variety meats, perhaps as early as next year.

[6] As regards analytical method, the method must be recognized and equivalent to the FSIS method, such as PCR-BAX.

FSIS Finished Ground Beef Sampling

In 2005, FSIS increased the number of samples taken for *E. coli* O157:H7. In the first eight months of 2005, FSIS conducted approximately the same number of samples it drew in all of 2004 (coincidently, the number of positive findings are the same for both years).

As discussed above, in absence of any contrary information, a positive FSIS *E. coli* O157:H7 finding will implicate: all product manufactured from the shipment of "same source materials" and any other product manufactured over the same food contact surfaces as the same source materials, clean-up to clean-up. This can implicate multiple days, especially when the raw material shipment was of a component that is used over time, such as hearts or cheek meat.

The first step in limiting exposure is to further differentiate the load of incoming raw materials. This is done by having the raw materials "lotted" based on test results. That way, the shipment can be divided into smaller units.

The second step is to minimize the number of different lots used when a sample is being taken for *E. coli* O157:H7. This would also include holding any unused combos/boxes from the "lot" until the sample results are reported. In addition, an establishment should also look to see if combos/boxes from the lot were used in previous production. If so, and the finished product was shipped, the establishment should let the inspector know that the sample could implicate shipped product. Under agency policy, a sample is not to be taken if the establishment did not have an opportunity to hold all product implicated by the sample.

The third step is to address the issue of what products could potentially have become cross contaminated through common food contact surfaces. Even though clean-up to clean-up is no longer determinative as to all product potentially implicated, the establishment must consider potential cross contamination in determining what production is implicated by a sample.

There is another way an establishment can minimize the amount of product potentially implicated by a positive agency finding. As part of the sample procedure, the FSIS inspector randomly selects a time to draw a sample. If the time selected is late in the day, the entire production before the sample could be implicated given common contact surfaces and common lots. However, FSIS has officially indicated that if: (a) there is a sound basis for the lotting of raw materials and (b) the establishment has previously explained its lotting/production practices to the in-plant inspector -- when the inspector randomly selects a time, the establishment can demonstrate to the inspector what raw materials would be used at a time randomly selected. By so doing, the establishment can run the selected product at the start of operations and follow with a pre-op cleaning/sanitizing. Provided the relevant raw materials and sampled finished product is held, the remainder of the day would be free to ship.

One final note on FSIS testing, if the establishment is conducting routine intensive product testing (multiple samples/analyses per day), FSIS will treat its positive the same as an establishment's positive. This means the positive period plus a period to either side (the "window") will be implicated. Barring an establishment positive the same day in a different period, the remainder of the day outside the window is free to ship.

Some Helpful Hints

It is important that establishments develop and implement a normal lotting and production system, and that this is followed on a routine basis because the Agency does not want lotting and/or production changes being made only when samples are being pulled – the Agency is trying to test the "normal" system. Based on the above, there is some general guidance that can be given for trim and ground beef producers:

For trim producers:

- Test (using a recognized methodology) ***all*** raw materials intended for raw ground use with a scientifically sound sampling program – that way if an FSIS sample tests positive for *E. coli* O157:H7, the only product implicated will be the combos from which FSIS sampled. If the establishment does not conduct any testing, the entire day is suspect.
- Work with the FSIS IIC now, so that there is no confusion as to what product is implicated when FSIS begins its regulatory sampling and analyses.
- Obviously, if FSIS' sample tests positive, the agency will expect the establishment to conduct a review of its total food safety system for all slaughter dates and fab dates involved, just as if the establishment's sampling yielded a positive.

For grinders:

- Purchase raw ground beef components which have been tested for *E. coli* O157:H7 using a scientifically "sound" sampling program.
- Understand the suppliers' lotting procedure so combos/boxes within the same lot can be identified and kept separate when necessary.
- When ground beef is to be sampled for *E. coli* O157:H7, identify the lots of raw materials in the blend at the time the sample is drawn and hold any unused combos/boxes from these lots and any finished product previously made from the lots until the test results are back. If finished product has shipped, let inspector know before the sample is sent to the FSIS laboratory.
- Manage raw material inventory so that partial lots are not held any longer than necessary.
- Work with the inspector to ensure he/she understands the establishment's lotting/scheduling procedures so that the product selected to be sampled by FSIS at a random time can nonetheless be run at the beginning of the shift.

Conclusion

Hopefully, this Guide has proven useful. If you have any questions or desire additional information, please contact:

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