

## **MODULE 8**

### ***E. COLI* BASIC AND OTHER COMPLIANCE/NONCOMPLIANCE**

#### **OBJECTIVES**

At the end of this module, participants will be able to:

1. Identify the role of in-plant inspection personnel in *E. coli* testing verification.
2. State the regulatory requirements for *E. coli* plans/procedures
3. Verify that *E. coli* plans/procedures meet regulatory or performance standards requirements.
4. Document findings and take enforcement actions when regulatory requirements are not met.
5. Use noncompliance trend indicators.

## MODULE 8

# ***E. COLI* BASIC AND OTHER COMPLIANCE/NONCOMPLIANCE**

### **Introduction**

In March 1997, an FSIS *E. coli* Special Team began visiting plants to determine whether they were in compliance with the basic regulatory requirements for *E. coli* testing. After HACCP training, FSIS in-plant inspection personnel will be responsible for ensuring compliance with the regulatory requirements for *E. coli*.

Determining whether the *E. coli* requirements are met by an establishment is divided into two parts: “basic” compliance/noncompliance and “other” compliance/noncompliance. Basic compliance/noncompliance addresses certain regulatory requirements the establishment must meet, whereas, other compliance/noncompliance is concerned with the actual execution of the requirements.

### **Basic Requirements**

Slaughter establishments must meet 3 basic regulatory requirements, §§ 310.25 or 381.94 (a) (2) (I), (a) (1), (a) (1) (iii), and (a) (4).

These 3 basic requirements that must be met in all slaughter establishments are:

1. The establishment must have a written *E. coli* specimen collection procedure.
  - The procedure must identify an establishment employee(s) (job title or name) designated to collect *E. coli* samples.
  - The written procedure must address the location(s) of sampling (i.e., the physical location in the plant where the sample is collected).
  - The procedure must address how the establishment will achieve sampling randomness.
  - The written procedure must address how *E. coli* samples will be handled to ensure sample integrity.

If the plant does not have written specimen collection procedures basic noncompliance exists.

2. The establishment must collect and analyze samples for *E. coli*.  
If the plant is not testing for *E. coli*, basic noncompliance exists.
3. The establishment must record the *E. coli* test results.  
Regardless of the sampling method (e.g., excision or sponging) the establishment must record the results on a control chart or table.  
If the plant is not recording results, basic noncompliance exists.

## **Basic Compliance/Noncompliance**

Perform procedure 05A01 to determine the establishment basic compliance/noncompliance for the *E. coli* requirements when a plant comes under inspection or changes its *E. coli* sampling plan. The *E. coli* special team performed the initial basic compliance procedure. If the basic procedure has been conducted by the special team, it is **not** necessary to conduct procedure 05A01 again when HACCP is implemented. Use the *E. coli* Testing Basic Compliance Checklist, FSIS Form 5000-3, as a memory-jogger when performing the procedure. When noncompliance is found, Form 5000-3 is attached to the file copy of the NR. If noncompliance is not identified, only the establishment identifying information is completed at the top of the page, and Form 5000-3 is filed in the government file. It is maintained like other official documents. A copy of the form is in Workshop 1.

## **Basic Documentation**

What happens if you conduct procedure 05A01 and find noncompliance with the basic regulatory requirements?

1. The IIC immediately withholds operations until compliance is attained.  
(Note: If the noncompliance is a simple omission, like forgetting to enter the name of an employee designated to collect samples in the written procedure, the IIC is authorized to allow operations to continue.)
2. Notify plant management of the noncompliance.
3. Document the noncompliance on a Noncompliance Record. Do not mark a trend indicator on the NR for this basic noncompliance. Give a copy of the NR to plant

management as soon as possible, or at least by the end of your tour of duty. Attach the basic checklist to the file copy of the NR.

4. Notify the District Office.

## **Basic Enforcement**

Upon determining that an establishment has failed to meet the *E. coli* regulatory testing requirements of 9-CFR-310.25 and 381.94 (basic noncompliance for meat and poultry) the IIC begins enforcement action by withholding inspection and contacting the District Office.

Once notified, the District Manager will have a Compliance Officer (CO) visit the plant to initiate and develop an investigative case file. The District Manager will instruct inspection personnel on additional appropriate in-plant regulatory action on a case-by-case basis.

## **Other Requirements**

Other requirements are met if the plant successfully executes the activities addressed in the written procedure, analyzes samples, and keeps records of test results.

## **Other Compliance/Noncompliance**

When scheduled by PBIS, FSIS personnel must perform procedure 05A02 to determine compliance with other requirements of the *E. coli* rule.

Noncompliance exists if:

1. The establishment is not collecting samples from the type of livestock or poultry that it slaughters in the greatest number.
2. The establishment is not collecting samples at the location in the slaughter process required by the regulations.
3. The establishment is not collecting samples by sponging or excising tissue from the required sites on a livestock carcass, whole-bird rinsing or sponging on the required sites of a turkey carcass or whole-bird rinsing chickens.
4. The establishment is not collecting samples at the required frequency.

5. The establishment is not sampling randomly as per its written procedure.
6. The establishment is not having the samples analyzed at a laboratory using an AOAC Official method or another method that has been approved and published by a scientific body.
7. The establishment's records of test results do not include at least the most recent thirteen test results.
8. The establishment's records do not express *E. coli* test results in terms of colony forming units per square centimeter when excision tests are used for cattle and swine or sponge tests are used for cattle, swine, or turkeys; or test results are not expressed in colony forming units per milliliter when the whole bird rinse method is used.
9. The establishment is not retaining records of test results for twelve months.
10. Table 1 in the regulations does not include applicable m/M criteria, and the establishment is not using a statistical process control technique to determine how much variation in test results is within normal limits.
11. Table 1 in the regulations includes applicable m/M criteria, and the establishment is not determining whether it is operating within these criteria.

The *E. coli* Testing Checklist for Other Compliance/Noncompliance, FSIS Form 5000-4, will be available for use in the field. Much like the Basic Checklist, it will allow you to consider specific "other" requirements and make individual determinations about compliance. It is also attached to the file copy of the NR when noncompliance is found or maintained in a government file with only establishment identifying information completed when noncompliance is not observed. It is maintained like all other government documents. A copy of this form is in the workshop section of this module.

## **Other Documentation**

When "other" noncompliance is identified, it is documented on a Noncompliance Record. The trend indicator marked on the NR will always be "other".

As soon as possible, or at least by the end of your tour of duty, give a copy of the NR to management. The establishment should respond to the NR either verbally or in writing.

## **Other Enforcement**

Other than documentation on an NR, the IIC will not take enforcement actions when **individual** “other” noncompliance is identified. There is no immediate withholding of inspection. However, further enforcement action might be necessary if the establishment **repeatedly** fails to implement appropriate immediate action or further planned action in response to “other”

noncompliance. In these cases, the IIC should notify the District Office. The District Office will assign a Compliance Officer to the case. The Compliance Officer will work with in-plant personnel to collect evidence and develop a case file. The District Manager will work with the Compliance Officer to determine additional enforcement action when necessary. As with basic noncompliances, decisions about necessary action for “other” noncompliances will be made on a case-by-case basis.

## **Sample Integrity**

In cases where the Agency guidelines are not followed and a comparable system of sampling is not used by the establishment, sample integrity can be jeopardized. Although ensuring sampling integrity must be addressed in the written specimen collection procedure, execution of sample collection to ensure sample integrity is not an “other” regulatory requirement. Instead, it is covered by Agency guidelines, and, as such, are not enforceable regulatory requirements. If inspection personnel observe circumstances that seem to jeopardize sample integrity, (e.g., freezing the sample, not shipping the sample on the same day it is collected) the District Office should be notified. Further investigation of the situation and any enforcement actions will be directed from the District Office.